ATTACHMENT 27

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

REBOTIX REPAIR LLC, Plaintiff, vs. INTUITIVE SURGICAL, INC., Defendant.	Case No. 8:20-cv-02274 HIGHLY CONFIDENTIAL INFORMATION - ATTORNEYS' EYES ONLY

EXPERT REPORT OF DR. T. KIM PARNELL

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I. QUALIFICATIONS AND EXPERIENCE

1. I am a trained Professional Mechanical Engineer (PE) licensed in the State of California. I hold three academic degrees: a B.E.S. in Engineering Science (with Highest Honors) from the Georgia Institute of Technology in 1978, followed by a M.S. and a Ph.D. in Mechanical Engineering from Stanford University in 1979 and 1984, respectively.

2. I am an ASME Fellow and an IEEE Senior Member. ASME is the American Society of Mechanical Engineers and IEEE is the Institute of Electrical & Electronics Engineers. These are the primary professional organizations for Mechanical and Electrical Engineering. There is significant cross-over in terms of combination electro-mechanical devices that need a multi-disciplinary background. I am a Board Member of IEEE-CNSV (Consultants' Network of Silicon Valley). I am also a member of IEEE-EMBS (Engineering in Medicine & Biology), IEEE-CE (Consumer Electronics), IEEE-VTS (Vehicular Technology Society), and IEEE-EPS (Electronics Packaging Society), which focuses specifically on the electronics industry and electronic components, manufacturing, and testing. I have served as an elected officer for several of these groups including as Chair of the IEEE-SCV (Santa Clara Valley) Section (the largest IEEE Section in the world with over 12,000 members in Silicon Valley), Chair of IEEE-CNSV (Consultants' Network of Silicon Valley), and Vice Chair/Treasurer of IEEE-VTS (Vehicular Technology Society). I am also a Member of ASM International (Materials Information Society) and SAE (Society of Automotive Engineers) International. I am Vice-Chair of the NAFEMS Composites Working Group (CWG) which focuses on simulation (Finite Element and other techniques) and on applications of composite materials in all industries.

3. I currently work as an independent consultant through Parnell Engineering & Consulting (PEC). I consult for high-tech industry and legal firms regarding patents, product liability, failure analysis, reliability, and product design/development issues. I have over 30 years

of professional experience using and combining analysis, simulation, inspection, and laboratory measurement to understand and solve engineering problems in a variety of industries and applications. Many of my projects involve products with both electrical and mechanical components and require a multi-disciplinary approach and expertise.

4. I have studied design and ruggedization of a variety of components and systems that must withstand severe service and environmental conditions in service such as medical devices, medical equipment, portable electronic devices, cell phones, and laptops. This experience further includes analyses of materials and material behavior, including elasticity, flexibility, and impact, in addition to deep technical experience with composites, polymeric materials, and manufacturing methods.

5. I have direct experience with manufacturing in multiple industries during my consulting career. This work began in the 1980s and includes various projects up to the present time. These applications include consumer electronics, biomedical, medical device, automotive, petrochemical, paper, metal forming, specialty materials and others. Equipment at issue often involves injection molding, metal forming, stamping, and machining, semiconductor packaging, pipelines and piping components, pressure vessels, sensors and control systems.

6. I began my professional career in 1978 at Bell Laboratories in Indianapolis, IN after graduation from Georgia Tech. I was a Member of Technical Staff (MTS) at Bell Labs with a focus on design and development of telephone electro-mechanical components. I worked at Bell Labs before and during my Stanford M.S.M.E. degree, and Bell Labs supported me financially for that degree and I remained on staff.

7. At Bell Laboratories, I worked specifically on keyboard and keypad applications and new design concepts for telephone sets. I built prototypes, studied, tested, and

developed designs utilizing stainless steel domes (caps), silicone rubber domes, piezoelectric polymers, and other novel technologies to simplify design, manufacturing, and assembly in addition to improving reliability. Environmental damage and reduced reliability were of particular concern for telephone sets, especially if the use environment was challenging (dirty, particulates, etc.). The need to develop more reliable and robust keypads and keyboards for these applications motivated this development and the focus on bringing innovative new technologies to the customers in the field. There was a strong emphasis on life-testing at both the component and the system level for all telecom related equipment. Reliability and robust design always represented a central focus throughout Bell Labs and the Bell System. These designs were developed with a keen sense of the importance of the manufacturing and assembly process to the in-service equipment.

8. I took a leave of absence from Bell Labs and returned to Stanford in 1980 to pursue a Ph.D. in Mechanical Engineering and completed that degree in 1984. My work on keyboard and keypad concepts utilizing domes and snap-through buckling behavior for providing a tactile response motivated my Ph.D. research work at Stanford.

9. After Stanford, I then joined SST Systems, Inc. as a Principal Engineer from 1984-1986. In 1986, I joined Failure Analysis Associates, Inc. as a Senior Engineer in the Mechanics and Materials Department. I was promoted to Managing Engineer in 1990. I worked on a wide range of projects as a consultant including aspects such as product failures, product design, and medical device development. The company went public in 1990 as "The Failure Group", but then changed its name to Exponent in the mid-1990's. In 1998, I was promoted to Senior Managing Engineer at Exponent. After 13 years at Exponent, I left to explore the medical device field and joined Rubicor Medical, Inc. in 1999 as Director of Research & Development.

When I left Rubicor in 2000, I started offering independent engineering consulting services under Parnell Engineering & Consulting (PEC). I have been an independent consultant from 2000 to the present. During that time, I also worked for MSC Software (2006-2010) in Product Management for finite element simulation software products, consulting, and customer applications.

10. At MSC Software I was a Senior Manager in the Product Management group where I contributed in areas such as the User Experience, testing and evaluation of nonlinear simulation tools, and also training. I was recognized as an expert in applications of nonlinear finite element analysis to industry products and challenges. I was an MSC Software technical staff member from 2006-2010 and I consulted with MSC Software extensively from 2000-2018.

11. I was a full-time member of the Mechanical Engineering faculty at Santa Clara University from 2010-2012 and taught classes in Manufacturing, Material Science, Mechanical Design, Finite Element Analysis (FEA), Composite Materials, and Kinematics & Mechanisms. During this time, I served as the Faculty Advisor for several Senior Design Projects. These "real world" Capstone Design Projects encompassed design, system integration, and manufacturing aspects and provided the students with a full product development experience. I also taught graduate courses in Mechanical Engineering at Stanford University from 1995-1996. I have delivered numerous invited presentations, short-courses, and seminars on a range of technical topics to professional organizations and companies. Some of the topics include Mechanical Design for Reliability (MDfR) courses tailored to specific types of products and industries, and Medical Device Technology. I also taught several courses involving the application of simulation and analysis tools and how to better utilize simulation in the design cycle to reduce prototypes, shorten development time, and improve product reliability.

12. My project work includes studies for a broad range of consumer products, equipment, and manufacturing methods. Over the years I have also consulted in the areas of structural mechanics, shock and vibration sensitivity, fracture and fatigue, robust design, and finite element analysis of structures. My practice often encompasses design, failure analysis, forensic investigation, root cause analysis, and reliability issues. My expert work often involves similar issues and often intellectual property matters. Keypad and keyboard concepts include mechanisms, interfaces, and physical design along with volume manufacturing considerations. Recent laptop patent cases involved keyboard technology for moisture resistance, and a laptop display mounting concept to allow the screen to fully pivot or rotate. I also studied enclosures for portable electronic devices for ruggedization and resistance to adverse environments. Hands-on inspection, disassembly, and sometimes destructive evaluations are typical components of projects for portable electronics and medical products.

13. A more comprehensive record of my professional background and technical qualifications is reflected in my curriculum vitae, which is attached hereto as Exhibit A. A list of my expert engagements is also included in my curriculum vitae.

14. My opinions and conclusions in this report are based on my years of professional experience in mechanical engineering, failure analysis, and other work in medical devices, medical instruments, consumer electronics, and other sophisticated technology devices. I have relied upon the documents and testimony listed in Exhibit B (as well as the materials cited in the text and footnotes of this report). I reserve the right to supplement or amend my report as new information becomes available.

15. I am not currently and have not previously been employed by Rebotix Repair LLC. Counsel for Rebotix retained me to provide my independent and objective analysis

of the issues in this case. I am being compensated for my time in this matter at the rate of $590 per hour and my compensation is not dependent on the outcome of this litigation.

II. OPINIONS

A. Adoption of Opinions from Dr. Sharlin's Report

16. I have reviewed Dr. Joshua Sharlin's report. In multiple sections, Dr. Sharlin discusses the safety of repaired EndoWrists and comparisons between traditional laparoscopic instruments and EndoWrist instruments.[1] Throughout this report, I reference sections of Dr. Sharlin's report. I fully agree with these opinions on the safety of Rebotix-repaired EndoWrists and adopt them and incorporate them into this report as my own.

B. Summary of Key opinions

17. In my opinion, Dr. Howe's opinions and analysis are not reliable, are not supported, and are incorrect. Dr. Howe misunderstands the Rebotix service procedure, does not address detailed underlying documentation, and makes unfounded assertions about potential safety concerns.

18. It is my opinion that Rebotix's repair procedure ensures that EndoWrists can continue to be used safely.

19. It is my opinion that the Rebotix repair process results in instruments that have a higher degree of safety and reliability than new EndoWrists manufactured by Intuitive.

20. It is my opinion that Intuitive's use counter does not promote patient safety. The use counter has numerous flaws that demonstrate that it does not function to ensure safety and reliability.

[1] *See e.g.*, Sharlin Report, Sections 2.4.2.1 and 2.4.2.2.

21. In my opinion, neither Dr. Howe nor Intuitive have any basis to assert that EndoWrists repaired by Rebotix are less safe than new EndoWrists sold by Intuitive.

22. My other opinions are expressed below.

III. TRADITIONAL LAPAROSCOPIC INSTRUMENTS ARE ROUTINELY REPAIRED. ENDOWRISTS CAN BE SIMILARLY REPAIRED.

A. Traditional laparoscopic instruments and EndoWrists have many similarities.

23. Both traditional laparoscopic instruments and EndoWrists are designed to be used in minimally invasive surgeries. The ends of laparoscopic instruments and the ends of EndoWrists are virtually indistinguishable because each instrument is expected to perform the same function in a surgery. For example, a traditional laparoscopic scissor and an EndoWrist scissor are both designed to cut tissue. They perform essentially the same function.

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MR. ERWIG: Q. Mr. DeSantis, one of the instruments that's described here is scissors; right?
A Yes.
Q And your understanding of the function of scissors in surgery is to cut tissue; right?
A Yes.
Q And the scissors on the end of the EndoWrist, those are designed to cut tissue; right?
A Yes.
Q And the scissors on the end of traditional laparoscopic instruments, those are designed to cut tissue as well; right?
A Yes.

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Q And what it means for something to be similar in terms of intended use is that those two things are performing essentially the same effect in surgery; right?
A Yes.

- DeSantis depo tr., 95:13 – 96:5

24. Intuitive's own initial 510(k) submissions and its understanding of EndoWrists confirms this functional similarity.[2] The working ends and elements of the EndoWrists are "essentially identical in size and shape to the predicate devices" – laparoscopic instruments.[3] And the EndoWrists themselves "are essentially identical in terms of shape, size, function, and tissue effect" to the endoscopic instruments that Intuitive identified as predicate devices in its initial 1999 510(k) submission to the FDA.[4]

25. Dr. Howe acknowledges these extensive similarities in his report: EndoWrists "are in many external and functional ways similar to traditional instruments." [5]

B. <u>Traditional laparoscopic instruments are routinely repaired</u>

26. Traditional laparoscopic instruments experience failures as they are used.[6] The scissors at the end of traditional laparoscopic devices dull and are not sharp enough to cut tissue during a surgery.[7] Graspers become misaligned or unable to grasp with sufficient force.[8] And needle drivers loosen such that they cannot hold a needle as tightly as required for precise use during surgery.[9]

27. Hospitals measure wear on these instruments by assessing whether they are performing their required function in surgery.[10] Hospitals will assess a traditional instrument both in a pre-operative inspection and during actual surgeries. If an instrument is not performing its

[2] Sharlin Report, ¶ ¶116 – 119.

[3] Johnson depo tr., 28:12-17.

[4] Id. at 31:8-23.

[5] Howe Report, ¶34.

[6] DeSantis depo tr., 134:21-23.

[7] Id. at 134:24 – 135:1.

[8] Id. at 135:2-5.

[9] Id. at 135:6-8.

[10] Harrich, depo tr., 36:5-8.

function appropriately, hospitals will repair those instruments. It is a standard practice of hospitals to repair instruments used in traditional laparoscopic surgeries.[11] In those repairs, the traditional instruments are cleaned, aligned and bent into shape, sharpened, and inspected under a microscope.[12] The continued reuse and repair of those instruments allows the hospital to continue to use the instruments for surgeries.[13] And hospitals will not repair or service a product if that repair could make the repaired product unsafe for use in a patient.[14]

28. Bob Overmars, the president of BPI Medical, a company that repairs traditional laparoscopic devices and has repaired "tens of thousands" of laparoscopic instruments, testified that traditional laparoscopic instruments can be used "dozens to hundreds" of times before being sent in for repair.

Q. One of the instruments you indicated you repaired is laparoscopic instruments; is that right?
A. That's correct.
Q. When did you first start repairing laparoscopic instruments?
A. Over 20 years ago.
Q. What is your best estimate of how many laparoscopic instruments BPI Medical has repaired?
A. Tens of thousands
…
Q. Is one of the laparoscopic instruments that BPI Medical repairs the Deknatel Snowden-Pencer Diamond-Touch?
MR. FOLGER: Objection to form.
BY MR. LYON:
Q. I didn't hear your response.

[11] See, e.g., Donovan depo tr., 29:14-18, Harrich depo tr., 32:17-33:3.

[12] Harrich depo tr., 33:5-12.

[13] Id. at 33:5-16.

[14] Id. at 26:9-12.

A. Yes, we do.

-Overmars depo. tr., 96:14-97:10.

29. Laparoscopic instruments in need of repair can suffer from unintuitive motion, insufficient grip force, dull or damaged scissor blades, and worn or damaged cables. Those failure modes are common in laparoscopic instruments in need of repair. And a hospital makes the determination to send in an instrument based on the wear it has experienced and its inability to perform functions in surgery.

Q. How many times is a typical laparoscopic instrument used before it's sent to you for repairs?
A. It could be dozens to hundreds.
Q. What determines if it's dozens or hundreds?
A. There will be lack of grip of the instrument jaws. There will be dull scissors. There will be broken or failed components.
Q. Are these some of the problems you see in a laparoscopic instrument in need of repair?
A. Absolutely.
Q. Is unintuitive motion one of the problems you commonly see in a laparoscopic instrument in need of repair?
A. Correct.
Q. Is insufficient grip force one of the problems you typically see in a laparoscopic
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instrument in need of repair?
A. Correct.
Q. Is dull or damaged scissor blades one of the problems you typically see in a laparoscopic instrument in need of repair?
A. Correct.
Q. Is worn or damaged cables one of the problems you typically see in a laparoscopic instrument in need of repair?

MR. FOLGER: I'll just object to the form.
BY MR. LYON:
Q. Again, I didn't get your answer. Remember to pause. Could you repeat your answer for me. The court reporter may have got it, but I didn't hear it.
A. Correct.
Q. Are these the sort of prob -- withdrawn.
Do you consider these common problems in laparoscopic instruments that you repair?
A. Yes.

-Overmars depo. tr., 98:10-99:20.

30. Mr. Overmars and his company have years of experience with both EndoWrists and traditional instruments. In comparison to traditional instruments, EndoWrists are more robust and well-made.

How would you compare how well made EndoWrists are relative to traditional laparoscopic instruments?
MR. FOLGER: I'll still object to the form.
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A. In our 25 years of experience of repairing endo laparoscopic instruments, the EndoWrist is built like a Hummer and the majority of all other laparoscopic instruments are like Ikea. The Intuitive EndoWrist is much more robust, much more uniquely designed, and just simply a way better, longer lasting instrument than a traditional laparoscopic instrument.

-Overmars depo tr. 101:22-102:8

31. Mr. Overmars' testimony that EndoWrists are "more robust" and "longer lasting" as compared to traditional laparoscopic instruments was borne out by my own

observations at Rebotix's facility. The construction of the EndoWrist was more durable than the construction of similar laparoscopic instruments. I would expect that EndoWrists could withstand more uses between repairs than traditional laparoscopic instruments.

C. EndoWrists can be routinely repaired in the same manner as traditional laparoscopic instruments.

32. EndoWrists have similar failure modes as traditional laparoscopic instruments. For example, the scissors on EndoWrists dull over time and are unable to cut tissue.[15] And similarly, the graspers on an EndoWrist become misaligned, and the needle drivers are not able to hold a needle as tightly as required for reliable surgical use.[16]

33. Hospitals also inspect EndoWrist instruments prior to surgery to determine whether there are any issues with the EndoWrist prior to surgery. And failure modes on EndoWrists, just like on traditional laparoscopic instruments, are obvious.

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Q. Does your hospital undertake any inspection efforts of an EndoWrist before it's used in a surgery?
A. Absolutely.
Q. What process does your hospital undertake to inspect an EndoWrist from Intuitive before it's used in a surgery?
A. So the inspection process will start in central sterile processing. There is multiple steps on processing and packaging those instrumentations, protecting the tips on them.
Once they're packaged, sent through sterile processing, they come into the room. The scrub tech, when they open the trays, will examine them on the field, make sure that the jaws are open and close, that the -- you know, everything is clean, that there

[15] DeSantis depo tr., 213:22-25.

[16] Id. at 135:2-8.

is no dried blood, that the ports are working.
And then the first assist will do that also.

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Q. Are traditional laparoscopic instruments used in nonrobotic surgeries inspected in the same way as the EndoWrists are?
A. Yeah, there is a little bit of different process. Some of the robotic instruments are a little bit more complicated with their flushing ports or how they're loaded, but, yes, all of our instruments are inspected.
Q. Do the EndoWrists sometimes fail the inspection?
A. Yes.

-Harrich depo tr., 40:9 – 41:11

34. The failure modes on EndoWrists that hospitals detect before the use counter has expired include misalignment of graspers, frayed cables, chipped tracks, or dull scissors.

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Q. What are some of the ways an EndoWrist might fail before it reaches its maximum number of uses?
A. So -- okay. So they -- the teeth might misalign. They'll get shifted so that they don't close completely lined up. They'll get a little bit offset.
The -- there is like wires, the bands. They fray, so there may be a frayed wire on them.

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They roll on a roller, a track, and that track may get chipped or the wire may come over the top of the roller. It's like a pulley. Or the scissors are dull and so they'll gnaw through the tissue instead of making a clean cut.

-Harrich depo tr., 41:18 – 42:4

35. Each of these failures is addressed through Rebotix's service procedure, as described below. And as discussed in Dr. Sharlin's report, Rebotix's repairs do not make any of these failures more likely.[17]

IV. REBOTIX'S SERVICE PROCEDURE ENSURES THAT ENDOWRISTS CAN BE REPAIRED AND USED SAFELY.

A. Rebotix's initial engineering processes established all of the specifications for the EndoWrists.

36. In my experience, reverse engineering the original specifications of an instrument is a common practice used by mechanical engineers in understanding instruments and their functions. Original specifications for instruments are often not published, and repair companies seeking to return an instrument to its original specifications need to conduct a thorough reverse engineering process. Reverse engineering typically involves two steps: testing a new instrument to understand and establish its specifications, and then testing a repaired or serviced instrument to ensure that it functions in the same manner as a new instrument. Rebotix performed these steps in its initial testing.

37. Before servicing EndoWrists, Rebotix extensively tested new EndoWrists to establish the baseline specifications for EndoWrists. As part of that complete evaluation, Rebotix assessed cable tension, wheel torque values, scissor sharpness, grasper alignment, insulation strength, and motion handling by the instrument.[18] This process was completed over the course of twelve to eighteen months.[19]

[17] Sharlin Report, ¶¶93-109.

[18] Fiegel conversation, *see also* REBOTIX075431-075433, REBOTIX075420, REBOTIX089137.

[19] Fiegel conversation.

38. And Rebotix documented the test results in a series of specification documents.[20] Those documents are used during Rebotix's repair process to ensure that the instruments comport with Intuitive's specifications.

39. After Rebotix documented the original specifications and developed its repair process, it employed third party testing laboratories to verify that its repaired EndoWrists complied with all applicable safety standards. Rebotix sent its repaired EndoWrists to SGS for electrical safety testing,[21] and IMR Test labs for materials testing.[22] And Rebotix then had its entire service process evaluated by DQS-Med to confirm that it complied with all applicable safety standards.[23]

40. The result of this robust initial reverse engineering process and subsequent testing is a repair process that safely and effectively ensures that repaired EndoWrists can continue to be used by hospital customers.

B. My experience with the Rebotix service procedure confirmed that the instruments serviced by Rebotix operate in the same manner as new EndoWrist instruments sold by Intuitive.

41. As part of my engagement in this matter, I inspected the Rebotix Repair facility in St. Petersburg, Florida. I was able to observe several complete EndoWrist repair processes, compare EndoWrists repaired by Rebotix to brand new EndoWrists sold by Intuitive, and examine a number of EndoWrists that Rebotix received from hospital customers that Rebotix had determined were not suitable candidates for repair. I interviewed Greg Fiegel, the Rebotix Director of Operations who is in charge of all Rebotix repair services for EndoWrists. I personally

[20] REBOTIX133235-REBOTIX133311, REBOTIX133337- REBOTIX133353, REBOTIX133373.

[21] REBOTIX128851

[22] REBOTIX092208

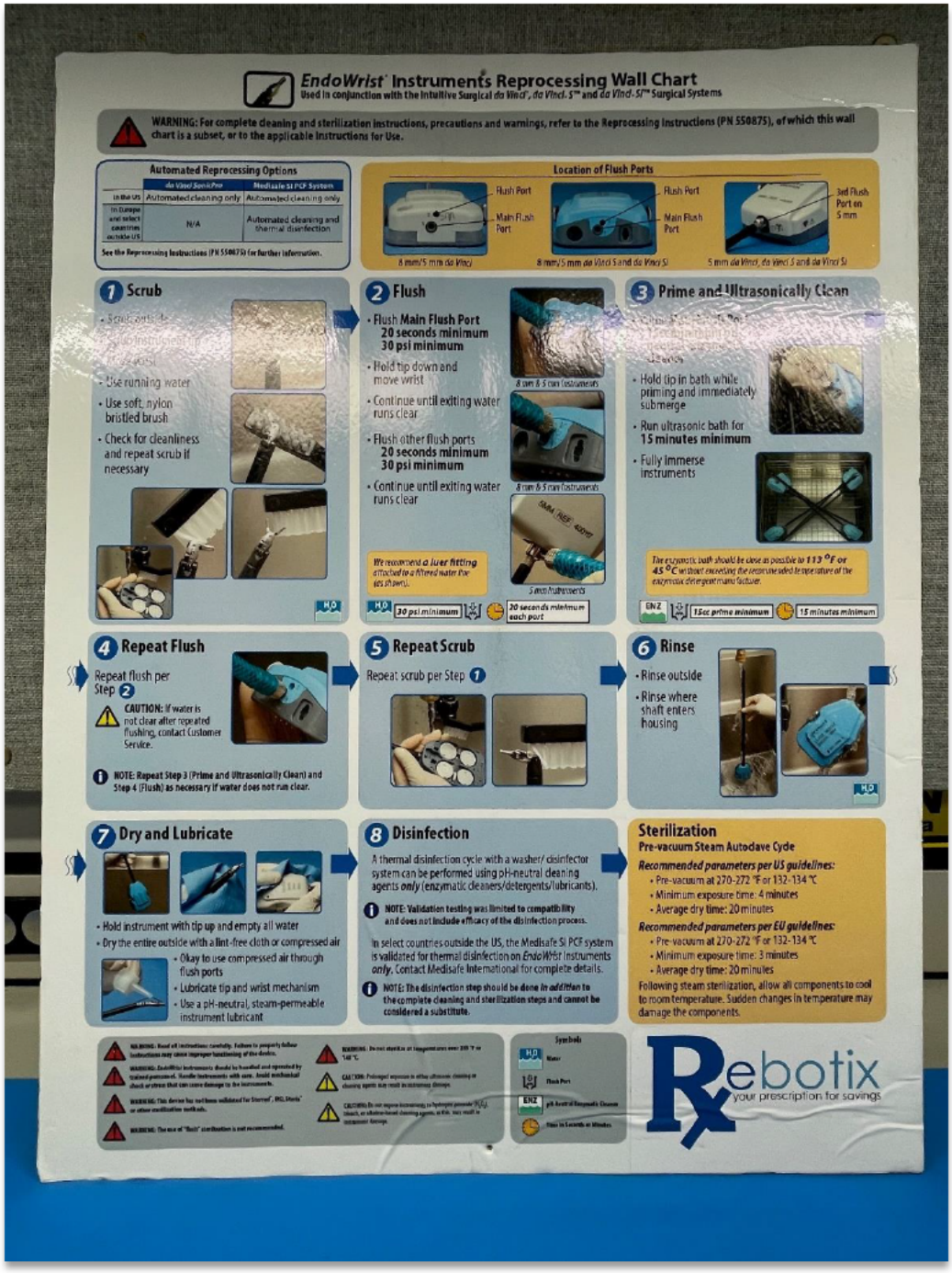
[23] REBOTIX083098

reviewed each step of the Rebotix Repair service process. That included the entire process from receipt of the EndoWrist devices from the customer, inspection, repair, and outgoing inspection before the devices are returned to the customer.

42. I was also able to examine the types of failure modes that EndoWrists experience. I encountered unintuitive motion, misaligned graspers, stretched cables, and fully broken cables, among other failure modes.

43. Dr. Sharlin's description of Rebotix's repair process in Section 2.4.2.2.2 of his report is an accurate overall description of the repair process. In my experience with the actual service process conducted by Rebotix, I documented some additional process details that I discuss in more detail below.

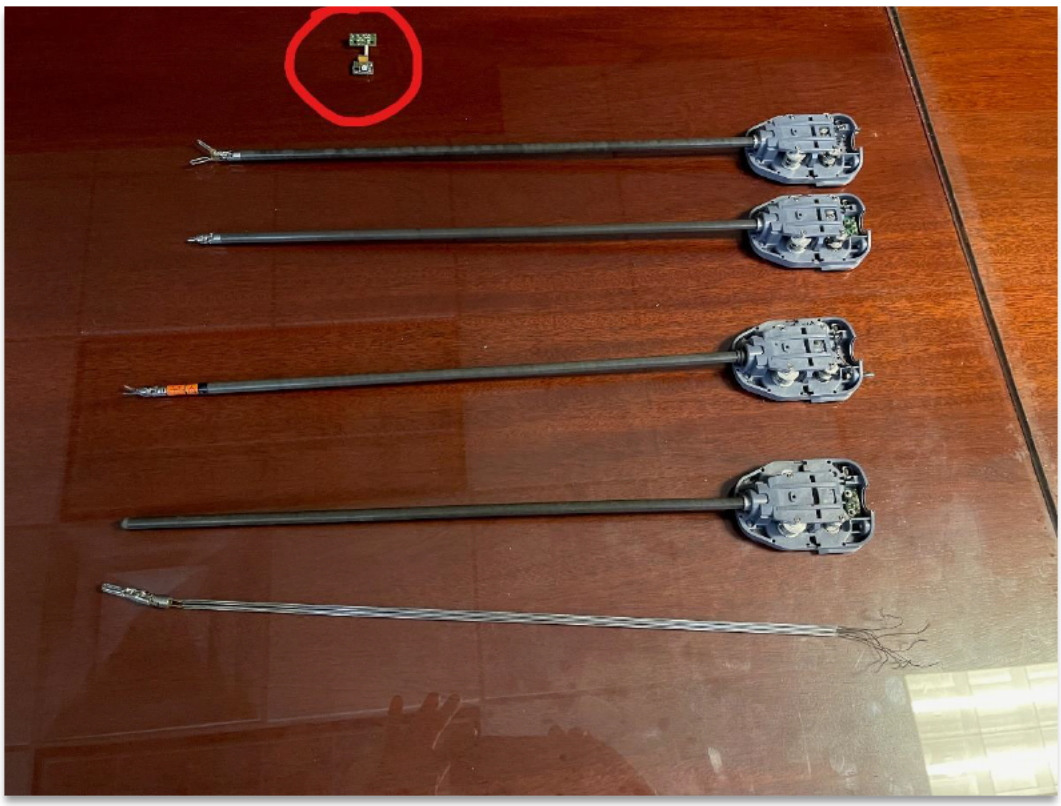
44. When an EndoWrist is received from a customer, Rebotix logs that EndoWrist in its inventory. Rebotix first scrubs, flushes, disinfects, and sterilizes that device, as shown in the *EndoWrist Instruments Reprocessing Wall Chart* below.



Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

45. After this initial process of ultrasonic cleaning and sterilization, Rebotix performs an initial inspection of the device. As part of that inspection, Rebotix removes the

housing at the proximal end of the EndoWrist. A Rebotix technician then performs an initial visual inspection of the entire device to scan for any obvious damage. Rebotix also checks the usage counter to determine the number of uses remaining on the device.



This photo shows a selection of the EndoWrists that Rebotix received. The housing on each EndoWrist is removed The bottom EndoWrist has had the cable system detached for illustration and examination (this is not a standard repair step). Rebotix's Interceptor assembly appears at the top of the image. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

46. After the initial visual check, a Rebotix technician uses an optical microscope at high magnification to examine the tool end of the EndoWrist (the scissors, graspers, etc), the exposed cables, and the pulley system at both the proximal and distal ends of the device. During this step, Rebotix looks for signs of cable fraying, cables misaligned with pulleys, pulley damage, damage to the main tube of the instrument, and any corrosion or contamination on the instrument bearings or the cables.

47. In addition to the visual inspection, when assessing whether the instrument is a candidate for repair, Rebotix operates each drive component through its full range of motion. During this process, Rebotix may determine that a cable has slipped off a pulley and become misaligned or that the device is otherwise unable to operate in its full range of motion.

48. For electrosurgical instruments, Rebotix performs the "Hipot Test" test sequence to ensure that the instruments' insulation and electrical isolation is functioning as expected. The test sequence indicates whether there is any damage or breakdown in the electrical insulation and isolation of the device or another issue that prevents the electrosurgical components from functioning safely in terms of their electrical behavior. The "Hipot Test" is described in greater details in Section IX. C.

This is a photo I took of the Dielectric Withstand Tester that Rebotix uses to run the "Hipot Test" to verify the insulation of electrosurgical EndoWrists. The programmed test sequence results in either a Pass or a Fail result. If the test reads "Fail" instead of "Pass," the instrument is not a candidate for repair. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

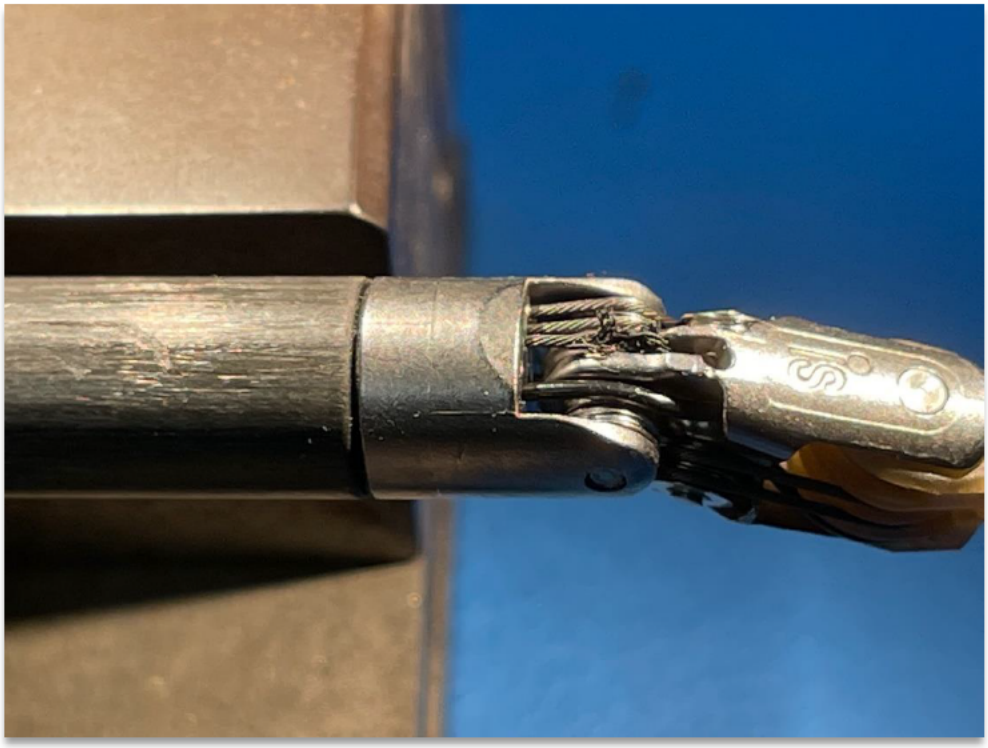
49. These initial inspections are meant to identify whether there is any existing damage to the EndoWrist device that indicates that the specific EndoWrist is "Unsuitable for

Repair." Instruments can be "Unsuitable for Repair" due to frayed or broken cables, damage to the pulley system (including sheared pins or broken bearings), or due to broken instrument tips. Similarly, if there is any damage to an electrosurgical instrument's insulation or the instrument fails the electrosurgical insulation/isolation test, the instrument will not be a candidate for repair.

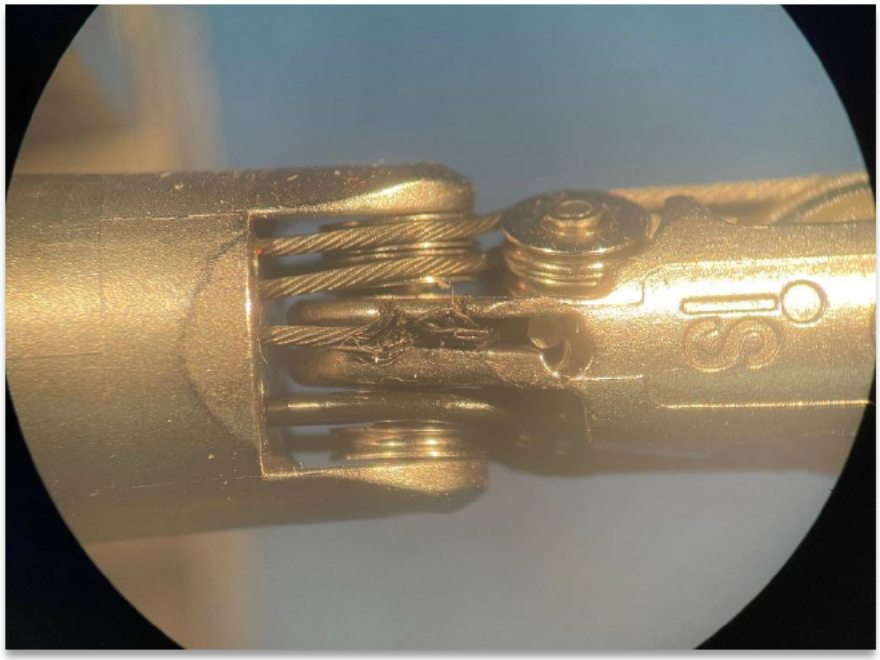
50. When an instrument is "Unsuitable for Repair," Rebotix will notify the hospital that submitted the EndoWrist for repair evaluation that the instrument is not suitable for repair. At that point, the device may be returned to the customer or remain in inventory at Rebotix and be labeled as "non-repairable."

51. I inspected several devices at Rebotix that were deemed to be "Unsuitable for Repair." Rebotix has an inventory of a number of unrepairable EndoWrists that it has received. As an example, an EndoWrist with a severed cable was not a repair candidate.

This picture is of an EndoWrist that Rebotix received from a hospital customer that was deemed "Unsuitable for Repair" due to cable damage. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.



This is a photo I took of the same EndoWrist. The frayed cable is clearly visible at the distal end of the EndoWrist. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

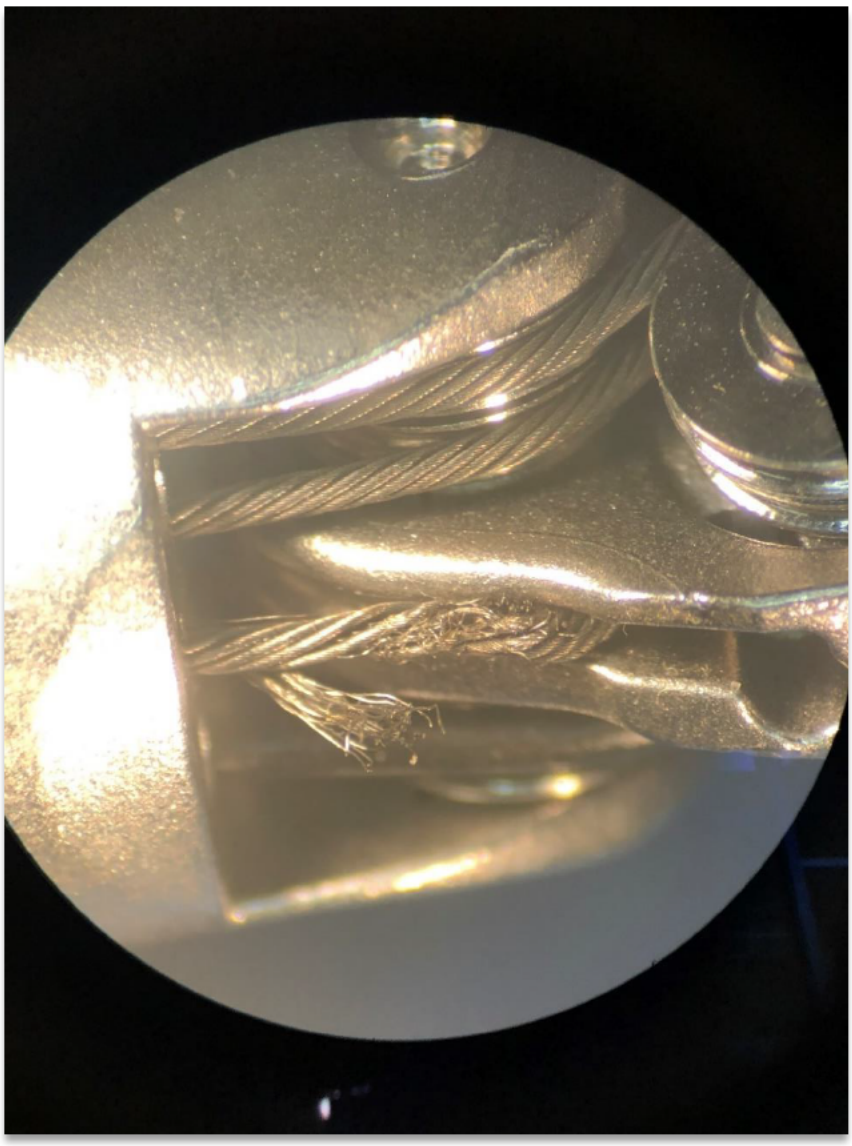


This is a picture of the same EndoWrist under an optical microscope. The cable tear is clearly visible. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

52. This EndoWrist still had remaining uses on the use counter, indicating that the failure was not a result of the instrument reaching its maximum number of uses. This instrument was received by Rebotix from a hospital that performed a visual inspection prior to surgery.

53. As another example, a PK dissecting forceps with four remaining uses was found to be unsuitable for repair due to a cable break.

Parnell, in-person visit to Rebotix facilities on August 10th, 2021.



Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

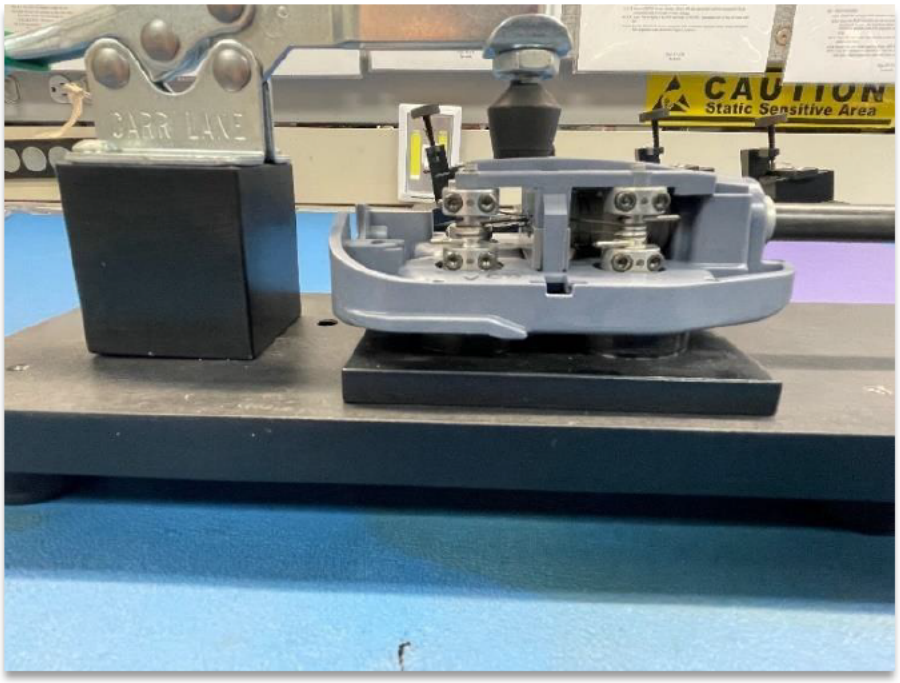
54. In my examination of the EndoWrists that were "Unsuitable for Repair," I did not detect damage due to wear on the instrument. For example, in the cables above, one of the cables in each instrument experienced a break, while the others were fully intact with no signs of fraying. The discrepancy between the cables (one displaying significant damage and the others showing no sign of wear) indicates that one cable was subject to damage from an external object

or from misuse. Other instruments with cables that I examined similarly reflected external damage and breakage, rather than wear.

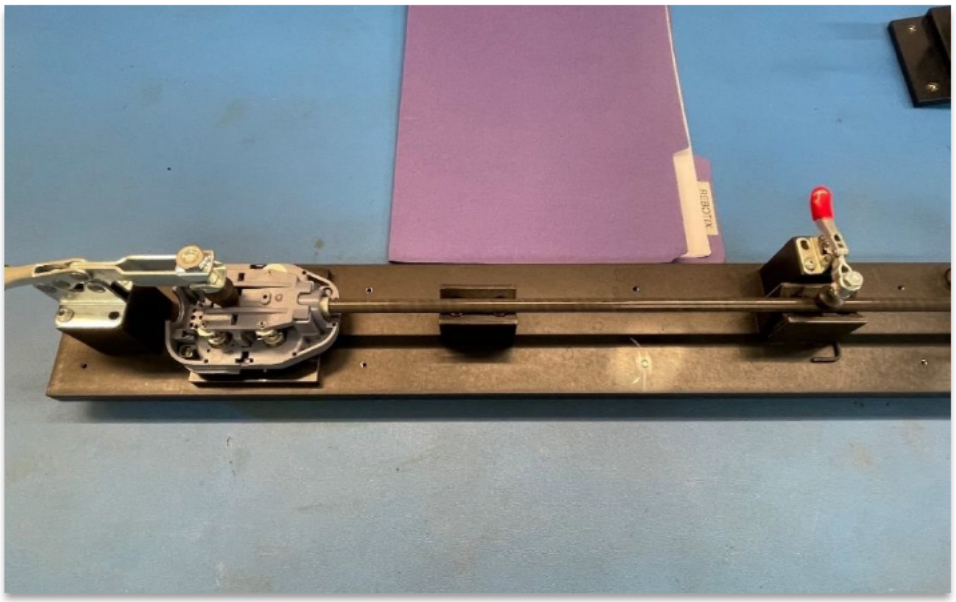
55. Once an instrument has been identified as a candidate for repair, Rebotix will perform a usage counter reset by installing the Interceptor component. Rebotix restores the usage counter to its original value; if the usage counter for an EndoWrist instrument sold by Intuitive is initially set to ten uses, Rebotix will reset the usage counter to the same value of ten uses. By setting the counter to another set of uses with the same value as the original, Rebotix ensures that the EndoWrist instruments will be sent in for inspection and repair after only a limited number of uses. By contrast, traditional laparoscopic instruments do not have a usage counter and, therefore, are not sent in for inspection and repair at regular intervals.

56. After the Interceptor is installed, Rebotix then performs any needed repairs on the tool end of the EndoWrists, such as sharpening scissors, aligning graspers, or ensuring sufficient tightness on needle drivers. Rebotix then makes any needed adjustments to the cables. Rebotix places the EndoWrist in a special fixture, and locks the device in its neutral position. This tensioning process involves adjustment of the cable tension and testing the EndoWrist range of motion to ensure that the tension is appropriate for surgical use. I personally tensioned the cables on an EndoWrist and was able to readily identify over-tensioning or under-tensioning of the cable. An under-tensioned cable fails to communicate movements precisely to the distal end, while an

over-tensioned cable requires excessive additional torque on the drive wheels at the EndoWrist proximal housing to operate.



Parnell, in-person visit to Rebotix facilities on August 10th, 2021.



The Rebotix designed fixture for cable adjustment and tensioning holds the EndoWrist steady in its neutral position and allows for cable tension to be calibrated. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

57. Finally, Rebotix will conduct a series of tests on the instrument as part of an outgoing evaluation. As part of that process, Rebotix verifies that the use counter reset was successful and that the instrument shows the original specified number of uses. Rebotix also evaluates whether the instrument's motion is functioning as expected, and whether the tool end of the instrument is performing appropriately (for example, cutting tissue or grasping). Rebotix also performs a second round of electrosurgical testing for electrosurgical EndoWrists to verify the integrity of the electrical insulation and isolation of the device.

58. If the EndoWrist passes all of the testing and inspection processes and is deemed fully functional, it is then subjected to another full cleaning process including scrubbing, flushing, disinfection, and sterilization. Although EndoWrists are not shipped back to hospitals as sterile and need to be reprocessed upon receipt, this cleaning process ensures that any debris or particulate matter is removed from the EndoWrist.

59. The EndoWrist is then repackaged and returned to the customer. Only an EndoWrist that satisfies both the Rebotix initial quality inspection and the Rebotix final inspection protocol will be returned to the hospital that originally sent that EndoWrist to Rebotix for repair.

C. Rebotix's repair process returns EndoWrists to their original functional specifications.

60. When Rebotix repairs an EndoWrist instrument, it performs a series of steps that return the EndoWrist to its original functioning specifications. It sharpens scissors, tightens loose cables, and ensures that the instrument performs in a manner equivalent to a new instrument.

61. Rebotix then resets the use counter to its original specification.[24] Rebotix does not increase the use counter to a value beyond the initially specified number of uses. And Rebotix does not otherwise alter the function of the instrument in any way.

62. The equivalent performance between EndoWrists repaired by Rebotix and those sold new by Intuitive has been confirmed by hospitals that have used the Rebotix repair service.

63. When Pullman Regional tested Rebotix-repaired instruments, they determined that "[t]here was no difference than the non-reprocessed instruments," and "didn't have any issues" with the Rebotix-repaired instruments.[25] None of the members of the surgery team at Pullman were able to identify any difference between the Rebotix-repaired EndoWrists and EndoWrists that had not been repaired or serviced by Rebotix.[26] In follow up interviews with the surgical teams that used Rebotix-repaired EndoWrists, Pullman learned "[t]hat the instruments still worked just like the nonrepaired ones. There was no difference."[27]

64. In stark contrast to the failures that hospitals periodically report on Intuitive's EndoWrists before their life counter is up, hospitals that have used Rebotix's repaired EndoWrists have not reported issues with unintuitive motion, dull scissor blades, or insufficient grip force.[28] Rather, hospitals reported that those instruments worked perfectly.[29]

[24] *See, e.g.,* REBOTIX162185

[25] Harrich depo tr., 37:1-25.

[26] Id. at 38:9 – 39:3.

[27] Id. at 40:2-8.

[28] Id. at 43:5-19.

[29] Id. at 74:9-14.

V. NONE OF THE ELEMENTS OF THE ENDOWRIST THAT DR. HOWE IDENTIFIES PRECLUDE REPAIR.

A. Dr. Howe's identified differences between traditional laparoscopic instruments and EndoWrists.

65. Dr. Howe discusses several differences between traditional laparoscopic instruments and EndoWrists that, in Dr. Howe's opinion, make EndoWrists unsuitable for repair.

66. First, Dr. Howe asserts that the motor interface of the EndoWrist produces unique constraints and failure modes.[30] Specifically, Dr. Howe asserts that the pins on input pulleys in the motor interface may slip or shear. He also asserts that bearings that enable low friction motion can fail.

67. Second, Dr. Howe discusses that the cable drives in EndoWrists "are more complex to design," may result in faster failures of the instrument, and are unsuitable for repair.[31]

68. Third, Dr. Howe asserts that the cleaning and sterilization cycles that EndoWrists are subjected to are "detrimental to instrument life."[32]

69. For each of these differences to make an EndoWrist unsuitable for repair, they would either (1) have to be such that they would be overlooked or ignored in the repair process, or (2) testing would need to confirm that repairs are not feasible or not possible.

70. I address Intuitive and Dr. Howe's lack of testing on Rebotix's instruments at length later in the report in XI., and explain why neither Intuitive nor Dr. Howe has any basis to conclude that Rebotix's instruments are unsafe. I now address why Rebotix's repair process takes each of the identified differences into account to effectuate a successful repair of EndoWrists.

[30] Howe Report, ¶24.

[31] Id. at ¶¶26-27.

[32] Id. at ¶28.

B. None of the differences preclude repair, and each is addressed by Rebotix's service procedure.

a) The Rebotix service procedure takes any failures in the motor interface into account.

71. As discussed above in Section IV. B., Rebotix inspects each EndoWrist when it is sent to Rebotix for repair. If Rebotix discovers that an EndoWrist that it receives has either of the issues identified by Dr. Howe (pin slipping/shearing or failed bearings) it will not repair that instrument. Pin slipping or shearing results in the instrument being unable to move or difficulty in mounting the EndoWrist to the da Vinci robot. Similarly, failed bearings result in the instrument being unable to adequately move the cables and roughness in the motion. Those issues would be detected in either the visual inspection of the components inside the instrument's proximal housing, or in Rebotix's cable tensioning procedure.

72. Further, there is no evidence that suggests that either of these failures are more likely to occur after Rebotix inspects and repairs an instrument. As part of Rebotix's outgoing instrument evaluation, it verifies that all parts of the motor interface are functioning as expected and that there are no issues that would prevent the instrument from functioning properly.

73. Moreover, these two failures produce consequences that are regularly encountered and addressed in surgery. The consequence of slipping or shearing of pins would be unintuitive motion, or difficulty mounting the EndoWrist to the da Vinci robot. Similarly, the failure of bearings that enable low friction motion would lead to excessive input torque requirements, input response that is rough, and unintuitive motion. Surgeons regularly replace instruments when they exhibit unintuitive motion during surgery.[33]

[33] Harrich depo tr., 43:20-44:19.

b) The Rebotix service procedure resolves any issues with the cable drive system.

74. Dr. Howe asserts that the unique cable system makes EndoWrists unsuitable for safe repair. I disagree with this assertion. The cable system found in an EndoWrist is not unique. Rebotix's service procedure identifies any cable issues that would make an instrument unsuitable for repair. Rebotix re-tensions cables to ensure that motion of the drive wheel corresponds directly with the appropriate response of the distal tool. Any unintuitive response before the repair is carefully eliminated with the cable tensioning step.

75. First, the cable system found in an EndoWrist is not unusual and is similar to cable systems found in some traditional laparoscopic devices. Some traditional devices have multiple degrees of wrist articulation, and do not set the tip to a specific angle. One instrument, the Maestro, is described as having its control mechanism "at a location similar to that of the da Vinci Surgical System's user interface."[34] The instrument similarly uses "tendon-driven" cable systems "which are routed through a cable guide into the steel rod and terminate at the handle mechanism."[35] The article describes the Maestro instrument design as "the design that most closely matches the interface of the da Vinci robot."[36] That instrument does not include a use counter. And there is no indication that the cables in that instrument cannot be re-tensioned if they experience wear.

76. Second, Rebotix only services EndoWrists that exhibit no signs of cable breakage, damage, or wear. There are three main components in a wire cable rope: a core, strands,

[34] Anderson, Patrick L., et al. "Robot-like Dexterity without Computers and Motors: a Review of Hand-Held Laparoscopic Instruments with Wrist-like Tip Articulation." Expert Review of Medical Devices, vol. 13, no. 7, 2016, pp. 661–672., doi:10.1586/17434440.2016.1146585., at page 6

[35] Id.

[36] Id. at 7

and filaments.[37] Filaments are bundled into "strands" around a central "strand core".[38] These strands are then combined together into a larger "wire", which is wound around a core of metal or fiber material. The construction of the cable provides for both flexibility and strength.

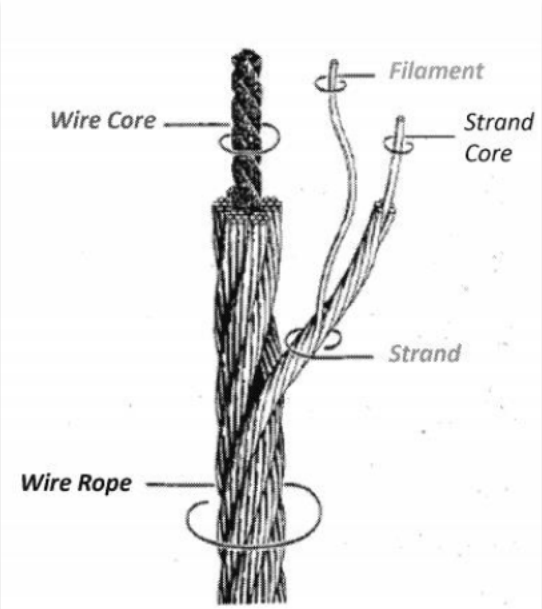


Figure 1: Typical wire rope assembly [2]

Intuitive-00029274

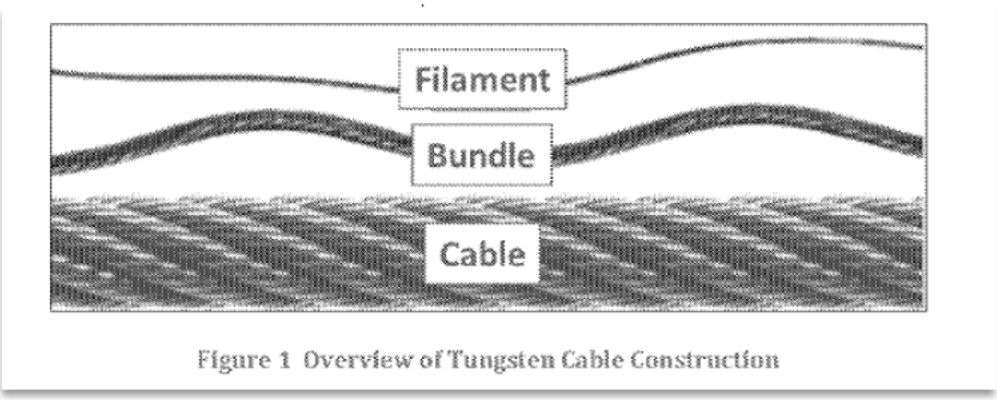


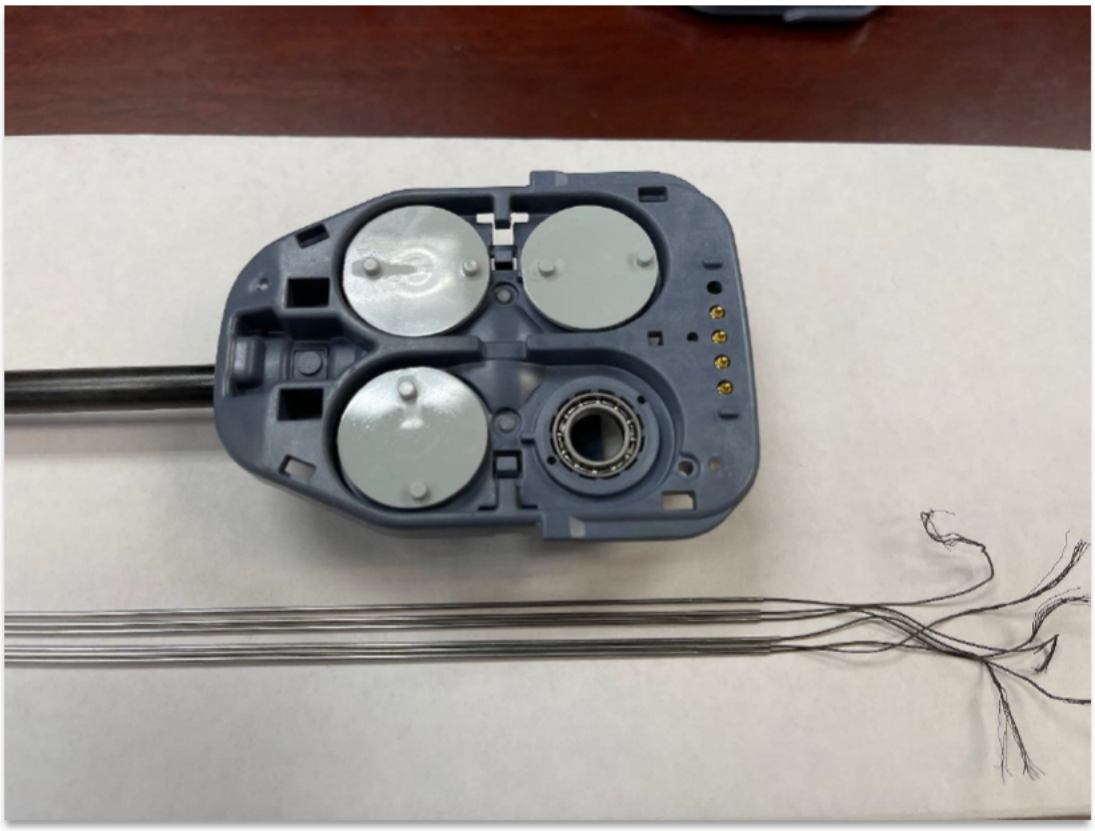
Figure 1 Overview of Tungsten Cable Construction

Another image of the cable construction is pictured in Intuitive's "Risk Benefit Analysis" document for tungsten drive cables. Intuitive-00536538

[37] Intuitive-00029274.

[38] Id.

77. The Intuitive EndoWrist design includes cables crimped onto rods at both the proximal and distal ends. The cables freely move at the proximal and distal end around the pulleys, but do not move within the rods. The central rods are inside the full length of the shaft and transmit input motion from the proximal drive to the distal tool.



The cables and the rods onto which those cables are crimped appear on the bottom part of this image. Parnell, in-person visit to Rebotix facilities on August 10th, 2021.

78. The pulleys at the proximal and distal ends of the instrument are the locations at which the cables could potentially experience wear. During its inspection process, Rebotix carefully examines the cables at both ends of the EndoWrist (the proximal and the distal end) under a microscope with at least 10x magnification. Rebotix pays particular attention to the

areas of cable/pulley contact and interaction. If any fraying or breakage is detected on even a single wire of the cable, the instrument is not considered a candidate for repair and will not be serviced.[39]

79. This process of careful inspection comports with guidance provided by Intuitive to avoid issues with the cable drive system. For example:

- 2-6: Before use, all instruments should be inspected for damage or irregularities.

Intuitive-00536543

80. Third, the Rebotix procedures address any slack experienced by a cable that would cause unintuitive motion. Rebotix evaluates whether the EndoWrist instrument's cable drive system has developed any slack that impedes the proper functioning of the instrument. And Rebotix tensions each cable in the instrument to remove any slack and restore proper tension. In addition, any instrument failures caused by cable failures do not pose risks to patients.

81. When Intuitive analyzed the potential risks associated with unintuitive motion that a cable failure could cause in a document titled "Risk Benefit Analysis: Frayed and Broken Tungsten Drive Cables, Pitch and Grip," it concluded:

> In any type of surgical procedure, an instrument that loses wristed motion as observed by the surgeon, whether upon insertion or later in the operation, will be immediately replaced with a properly functioning instrument. The immediate and long-range health effects of the use of such an affected instrument would be negligible.

Intuitive-00536541

82. For cable fragments falling into the patient, Intuitive concluded that cable fragments falling into the patient even in a critical intra-cardiac operation "would be easily retrieved and instrument replaced with only a brief delay in procedure."[40]

[39] Fiegel Conversation.

[40] Intuitive-00536542.

83. Intuitive summarized its conclusions about the ease of remedying potential cable-related issues during the procedure:

> The user manual provides guidance on the handling of instruments to prevent damage to the cables. However, if damage does occur and fragments or filaments are generated, the visible material can be removed through piece-wise removal or by suction and irrigation. If fragments, filaments, or particulate are not retrieved, the materials meet recognized standards for long term and short term biocompatibility. If the cable damage does not generate fragments, filaments, or particulate in the patient, the instrument can quickly be replaced with a backup instrument, as instructed in the user manual.

Intuitive-00536544

84. And ultimately, when assessing the impact of cable fraying or breakage on patients, Intuitive concluded:

> For both grip and pitch cables, the probability of adverse health effects is near zero.

Intuitive-00536543

c) Rebotix's service process addresses any instrument degradation from reprocessing.

85. Reprocessing cycles, according to Intuitive, slowly relax the cables in the instrument.[41] Evidence from research on reprocessing demonstrates that as cables are subjected to many reprocessing cycles, they are reduced in diameter and elongated, creating slack.[42]

86. Intuitive in its engineering has the ability to tighten cables.[43] But Intuitive has never attempted to repair loose cables on an EndoWrist.[44]

[41] McGrogan depo tr., 54:15-25.

[42] Intuitive-00029298.

[43] McGrogan depo tr., 55:9-18.

[44] DeSantis depo tr., 272:15-23; McGrogan depo tr., 55:20-24.

87. As discussed above, Rebotix tightens any slack cables during its repair process. And Rebotix has tested its repaired EndoWrists to confirm that they continue to function identically to new EndoWrists.

88. Dr. Howe claims that corrosion results from reprocessing. But Dr. Howe never cites any document or source that indicates that reprocessing leads to significant corrosion of the EndoWrist wire drive. Instead, he cites a Navy Wire-Rope Handbook that indicates that corrosion can be harmful to wire-ropes.[45] Moist, marine environments create rapid-pitting corrosion, which is not representative of the environment EndoWrists are used in.[46] Dr. Howe never provides any detail about the amount of corrosion that would be harmful to an EndoWrist cable system or even how a properly performed reprocessing cycle introduces corrosion.

89. And Dr. Howe's own cited handbook confirms that corrosion can be counteracted by "using a corrosion-resistant wire material such as stainless steel." [47] Intuitive's cable wires are composed of corrosion-resistant material: the rods are made of stainless steel, and tungsten cables are corrosion resistant. Intuitive's own cable supplier confirms that the Tungsten cables that it manufactures for Intuitive have "strong corrosion resistance." [48] Further, Intuitive uses a stainless-steel alloy (303 SS) for the rods in its cable construction.[49] 303 SS has "good corrosion resistance."[50]

[45] Howe Report, ¶29

[46] "303 Stainless Steel." Penn Stainless, 5 Dec. 2018, www.pennstainless.com/resources/product-information/stainless-grades/300-series/303-stainless-steel/.

[47] Navy Wire-Rope Handbook Vol 1. Page 3-16.

[48] "Tungsten." *Elmet Technologies*, www.elmettechnologies.com/tungsten/.

[49] Intuitive-00521056, Intuitive-0048179, Intuitive-00538053, Intuitive-00481167.

[50] Steel, Alro. "303 Stainless Steel." *303 Stainless Steel | Chromium-Nickel Stainless Steel | Alro Steel*, www.alro.com/divsteel/metals_gridpt.aspx?gp=0117.

90. Moreover, Rebotix's service process addresses any impactful corrosion. Rebotix extensively examines the proximal housing, its components, and the cable drive system for any sign of corrosion or degradation.[51] If any corrosion is detected, the instrument is not serviced. Moreover, the ultrasonic cleaning that the instrument is subjected to before being sent back to hospitals removes any corrosion, rust, or debris.[52]

VI. DR. HOWE CLAIMS THAT INTUITIVE'S USE COUNTER IS BASED ON SAFETY AND RELIABILITY CONSIDERATIONS. THESE ASSERTIONS ARE FALSE. THE USE COUNTER ON ENDOWRISTS HAS MULTIPLE FLAWS AND DOES NOT ASSURE PATIENT SAFETY.

91. Intuitive asserts that the use counter is an essential specification of the EndoWrist that ensures that EndoWrists can be used safely. This assertion is false.

92. First, Intuitive's use counter does not measure the wear that an instrument experiences during surgery, and an instance of "usage" itself is poorly correlated with wear because it does not take into account the time or complexity of different surgeries. As a result, the use counter cuts short the useful life of EndoWrists.

93. Second, Intuitive's use counter does not reflect the reprocessing cycles that an instrument undergoes. An instrument can be reprocessed ten times and still show the maximum available number of lives on the use counter.

94. Third, Intuitive's use counter does not take into account mishandling or misuse. An instrument can fail due to mishandling on its first use or on its twentieth.

95. Fourth, Intuitive's testing on the appropriate number of uses validates a preset target provided by marketing, rather than actually establishing the maximum number of uses an instrument can undergo before experiencing a failure.

[51] Fiegel Conversation, REBOTIX082680.

[52] REBOTIX077469.

96. Fifth, the use counter only indicates that the proximal end of the EndoWrist containing the use counter chip was mounted to the da Vinci robot in order to record a use and decrement the counter. There is no check on the condition or the instrument or an assessment of the instrument's operation; those checks must be performed by the hospital team. The shaft and distal tool end could be totally removed from the instrument and the usage counter would still be decremented if the surgeon attempted to operate the instrument. In this sense, the usage counter is meaningless as an indication of the EndoWrist's safe operation.

A. Use counter does not measure actual wear experienced by instruments in surgeries.

97. Intuitive's use counter does not measure the wear that an instrument experiences during surgery. And "usage" itself is very poorly correlated with wear. As a result, the use counter cuts short the useful life of EndoWrists.

a) Surgical procedures vary radically in amount of time and complexity, and result in different amounts of load and stress placed on each instrument used during surgery.

98. Laparoscopic surgeries range significantly in the amount of time required for surgeries. One study concluded that timing for the most common gynecological laparoscopic procedures ranged between 10 and 400 minutes (the article highlights that the "range of operating times is great" and a "relative lack of predictability in procedure times").[53] There are additional significant ranges in individual procedure times. For example, surgery for endometriosis might range from 10 to 240 minutes, while a hysterectomy might range between 25 and 400 minutes. (Id.). And procedure times are generally similar between robotic and non-robotic laparoscopic

[53] Shushan A, Mohamed H, Magos AL. How long does laparoscopic surgery really take? Lessons learned from 1000 operative laparoscopies. Hum Reprod. 1999 Jan;14(1):39-43. doi: 10.1093/humrep/14.1.39. PMID: 10374091.

procedures. (For example, one study determined that total operating time "did not differ significantly" between robotic assisted and non-robotic assisted laparoscopic cholecystectomies.[54]

99. And further studies have outlined the significant range in operative time from patient to patient even in the same type of surgeries. One study examining laparoscopic colon surgeries found ranges between 50 and 300 minutes for Ileocecal colectomies, between 62 and 330 minutes for sigmoid colectomies, and between 130 and 590 minutes for total abdominal colectomies.[55] This significant range in surgical time between patients undergoing the same surgery further illustrates the lack of uniformity in the time that instruments are used during surgery.

100. Instruments used in surgeries can be used in varying ways. Some instruments might be used for complex anastomosis (sewing or suturing), while other instruments might be used to grasp or hold tissue in a single position during the surgery.[56] Instruments might be used for short periods in very complex ways that places great strain on the instrument, or they might be used for long periods with minimal strain placed on the instrument.

101. This is why there is a variance in frequency of repairs for traditional laparoscopic instruments—they require repair service at different rates depending on how they are used in surgery. As discussed above, Bob Overmars testified that traditional laparoscopic instruments may be used "dozens to hundreds" of times before being repaired, and that the functional characteristics of the instrument, such as "lack of grip of the instrument jaws," and "dull

[54] Ruurda, Jelle P., et al. "Analysis of Procedure Time in Robot-Assisted Surgery: Comparative Study in Laparoscopic Cholecystectomy." *Computer Aided Surgery*, vol. 8, no. 1, 2003, pp. 24–29., doi:10.3109/10929080309146099

[55] Scheer, Adena, et al. "Laparoscopic Colon Surgery: Does Operative Time Matter?" *Diseases of the Colon & Rectum*, vol. 52, no. 10, 2009, pp. 1746–1752., doi:10.1007/dcr.0b013e3181b55616.

[56] McGrogan depo tr., 26:8-25.

scissors" determines when they require repair.[57] An instrument that is heavily used during multiple surgeries will experience more significant wear than an instrument that experiences minimal wear over the course of a much larger number of surgeries.

102. EndoWrists are similarly used for different amounts of time during surgery—they can be used for a few seconds, a few minutes, or for multiple hours.[58] And they are also used in different ways during surgery.[59]

103. A system designed to accurately track the wear that an EndoWrist experiences in surgery would take into account both the time that instrument has been used, and the complexity of the tasks that the instrument performed at minimum, in addition to potentially tracking other factors. Intuitive acknowledges that to accurately reflect the life left in an instrument or the wear that an instrument has experienced, one would want to take into account at least the time that an instrument is used in surgery and the complexity of the tasks that an instrument is performing in that surgery.[60]

b) <u>Use counter does not take into account any of this time or complexity in attempting to measure wear on an instrument.</u>

104. The use counter decrements a single life as soon as the EndoWrist is manipulated from the surgeon console regardless of the time an instrument has been used in surgery or the complexity of the instrument's use during surgery. And the remaining count does not in any way indicate what the EndoWrist was used for in prior surgeries

[57] Overmars depo tr., 98:10-16.

[58] McGrogan depo tr., 24:11-17.

[59] Id. at 26:8-25.

[60] Id. at 32:9-22.

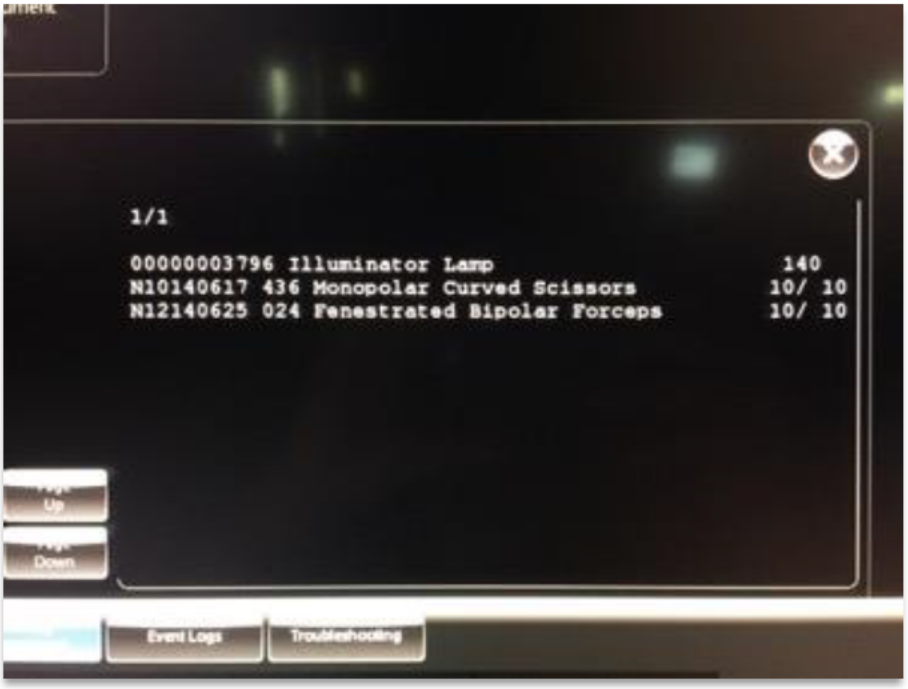


Image from Da Vinci Vision Cart

105. As shown above, the only information that the use counter displays is the serial number, the original number of uses and the remaining number of uses. Once an EndoWrist instrument is attached to the da Vinci robot and used in surgery in any way, a life is subtracted from the usage counter. [61] That is the case whether an instrument is used for ten seconds or two hours inside a patient's body.[62]

106. The dramatic time differences in the surgeries discussed in the previous section—between 10 minutes and almost 10 hours—are completely disregarded in the implementation of the use counter by Intuitive. For example, Anthony McGrogan, an Intuitive Vice President of product design was asked about two hypothetical EndoWrist instruments. One instrument was used for one minute in each of its ten uses before the use counter read zero. The other was used for one hour for each of its ten uses before the use counter read zero. Even though

[61] McGrogan depo tr., 17:13 –18:6.

[62] Id.

one instrument was only used for ten minutes in surgery and the other was used for ten hours, Intuitive requires each of those instruments to be thrown away because the use counter has been decremented to zero:

Page 24
Q. Now, let's assume that there is one instrument that's used ten times for about an hour
Page 25
per surgery.
Okay? Are you with me?
A. Yep.
Q. That instrument, according to Intuitive, is safe to be used for ten uses; right?
A. Yes.
Q. After those ten uses are up, Intuitive would tell the hospital you need to throw this instrument away; right?
A. Right.
Q. Now, let's take another instrument, same instrument. Let's use a cold grasper. It's used for one minute during surgery at different times.
A. M-hm.
Q. Was that a "yes"?
A. Yes.
Q. Intuitive would also tell the hospital to throw that instrument away after ten uses; right?
A. Yes.
Q. So the first instrument would have been used actually in surgery for ten hours; right?
A. M-hm.
Q. "Yes"?
A. The total surgical time is, I believe, ten -- yes, ten hours.
Page 26
Q. The second instrument would have been used in surgery for ten minutes; right?
A. Yes.
Q. Intuitive would tell hospitals that each one of those instruments needs to be thrown away;

6 right?
7 A. That's true.

-McGrogan depo tr., 24:24 – 26:7

107. Further, the complexity of different surgical procedures and the complexity of what each EndoWrist instrument is used for is not reflected in the uses remaining on the use counter. Mr. McGrogan confirmed that hospitals are not required to distinguish between simple and complex procedures.[63] For example, a grasper could be used to grasp tissue a single time during a surgery, or dozens of times. A single life being decremented from the use counter does not reflect that difference in any way.

108. Intuitive's purported inclusion of the use counter is to ensure patient safety, but the use counter itself fails to accurately take into account the key metrics of instrument wear. Measuring the life in an instrument should take into account both the time an instrument has been used and the complexity of the procedures for which the instrument was used—as acknowledged by Mr. McGrogan.

9 Q. Well, one way that Intuitive could measure
10 the life left in an instrument would be to measure
11 the instrument based on the time that it's been used
12 in surgery; right?
13 A. I think we talked that time is not a good
14 metric for measuring wear and tear.
15 Q. Well, the time takes into account how --
16 how long an instrument has been used in a given
17 procedure; right?
18 A. That's all it takes into account.
19 Q. Another thing that you might want to take
20 into account would be the complexity of what the
21 instrument is being used for right?

[63] McGrogan depo tr., 28:21-25.

22 A. That's right.
23 MR. RUBY: Object to the form of the
24 question. But it's been answered.
25 ///
Page 33
1 BY MR. ERWIG:
3 Q. I'm sorry. I didn't get your answer.
3 A. I said yes.

-McGrogan depo tr., 32:9 – 33:3

The use counter takes into account neither the time that an instrument has been used nor the complexity of the instrument's use during surgery.

Page 33
4 Q. Now, a decrementing of the life on a use
5 counter, that doesn't take into account either the
6 time that the instrument has been used in surgery or
7 the complexity of what the instrument did during the
8 surgery; right?
9 A. That's right, as far as I know.
10 Again, I don't know the details of the
11 algorithm. But, generally speaking, if you use it
12 in surgery, it's going to get decremented.
13 Q. That's the same whether it's been used for
14 ten simple short procedures or ten --
15 A. Yes --
17 Q. -- complex, long procedures; right?
17 A. Yes, yes.

-McGrogan depo tr., 33:4-17

109. The result of the Intuitive EndoWrist use counter that does not accurately track an instrument's useful life is that failures may occur prior to the use counter expiring. And at the same time, instruments that reach the maximum number of uses can still be safely used beyond that number. This has been borne out in the actual use of EndoWrists--Hospitals frequently

encounter failures on their EndoWrists before the use counter has expired, and frequently have EndoWrists with one remaining use on the use counter that show no signs of wear or failure.[64]

110. This is why traditional laparoscopic instruments do not have use counters. Instead, the instruments are routinely inspected, repaired, and continued to be used.[65] And if an instrument cannot be repaired, that instrument is discarded and no longer used in surgeries.

111. Hospitals measure wear on instruments by assessing whether they are performing the required function in surgery. EndoWrists frequently did not appear to be performing any differently by the end of their tenth use than they had on their first use.

Q. You stated that you believed EndoWrists had additional lives on them before you had to dispose of them when they reached their maximum use restrictions; is that right?
A. That's correct.
Q. Why did you believe that EndoWrists had additional lives on them?
A. Well, on the end of the tenth life, it wasn't working any different than it had been on the first life. There was no complaints by the physicians. If there were any, we'd take the instrument out of service or send it back in to Intuitive for repair if it still had lives left on it.
So if it's a grasper, it's a grasper. Is it grabbing the tissue like you think it should? As the physician says, it's feeling that tactile touch. You can't actually feel the touch, but on a console.

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But it's grabbing the tissue. They're liking what they're seeing. They're liking what they're feeling. So the instrument can still continue to be used.
Q. Is that how you determine whether a

[64] Harrich depo tr., 41:12-17. Harrich depo tr., 59:10-24, Harrich depo tr., 165 12:20, Donovan depo tr., 34:20-25, Donovan depo tr., 145:21-146:6.

[65] Donovan depo tr., 40:9-13, Harrich depo tr., 45:10-20.

6 traditional laparoscopic device should continue to be
7 used as well?
7 A. Yes, the functionality of it.

-Harrich depo tr., 35:9 – 36:8

B. Intuitive's use counter does not measure the number of times an instrument has been reprocessed.

a) Intuitive asserts that reprocessing cycles cause instruments to suffer wear and break down. If the number of reprocessing cycles is indeed a safety concern, it should be tracked by the use counter.

112. A reprocessing cycle is the process of cleaning and sterilizing the EndoWrist instrument for use in surgery.[66] An instrument is reprocessed even if it is not actually used in the surgical procedure—as long as the instrument enters the surgical field, it must be reprocessed by the hospital.[67]

113. Dr. Howe asserts that the cleaning and sterilization cycles that EndoWrists are subjected to during reprocessing are "particularly detrimental to continuing reliable operation."[68] And Dr. Howe cites an Intuitive document that states that "[w]hen the number of reprocessing cycles far outnumber the number of uses, early failures can occur."[69]

114. Based on Intuitive's assertions regarding the impact of reprocessing cycles on the safe operation of EndoWrists and the potential for early failures, I would expect that the number of reprocessing cycles an instrument has undergone would be tracked by the EndoWrist usage counter.

[66] McGrogan depo tr., 21:11-15.

[67] Id. at, 19:11-18.

[68] Howe Report, ¶28.

[69] Id., citing Intuitive-00004692 at 00004700.

b) Intuitive's use counter does not track reprocessing.

115. But Intuitive's use counter does not in any way take into account the number of times that an instrument has been reprocessed. The use counter only tracks the number of times that an instrument has been mounted to the da Vinci robot and manipulated in surgery.

116. Hospitals could easily reprocess an instrument many more times than indicated by the use counter. For example, an instrument that enters the surgical field would need to be reprocessed, even if it was never attached to the robot and never used for surgery. That same instrument could be reprocessed ten times (or more) before it is ever activated for use in surgery. But the use counter would still read as having ten available uses.

117. Intuitive provides reprocessing instructions that inform hospitals about the maximum number of reprocessing cycles for an instrument.[70] But as of March 2020, Intuitive's own internal documents stated that "no instruction is given on what to do with an instrument that reached the max RC before life expires".[71] Further, Intuitive is strictly relying on the hospital to track the number of reprocessing cycles that any given instrument experiences.

118. The failure of the use counter to track the number of times an instrument has been reprocessed is a further indication that the use counter does not ensure instrument safety.

[70] *See, e.g.*, Intuitive-00004700.

[71] Intuitive-00624802.

C. The usage counter does not take into account mishandling or misuse.

a) Instruments frequently experience failures due to mishandling or misuse.

119. Intuitive's RMA data show that instruments frequently experience failures prior to the usage counter expiring that are caused by misuse, mishandling, or improper cleaning during reprocessing.[72] For example:

a. Cable breaks:

120. Cable break during procedure, causing a "segment of the conductor wire sticking out from the yaw pulley" and the broken piece to go missing "as a result of the breakage". The failure was caused by mishandling/misuse, such as excess force applied to distal end of the instrument .[73]

121. The forceps were found to have a "frayed grip cable at the distal idler pulley". The frayed cable strands "stuck out at the wrist" of the instrument. This failure is "most commonly caused by mishandling/misuse, such as excessive contact with abrasive or hard surfaces during transport or reprocessing".[74]

122. The bipolar forceps were "found to have a broken conductor wire at the yaw pulley". The instrument was also "found to have damage at the conductor wire's insulation" and "failed the electrical continuity test". This failure is "commonly caused by mishandling/misuse, such as collision of the instrument with a sharp object".[75]

[72] Intuitive-00695006.

[73] Id. at Tab 1, Row 39574.

[74] Id. at Tab 1, Row 140045.

[75] Id. at Tab 1, Row 96870.

b. Grip failure:

123. Tips of instrument grips were severely bent during the procedure, causing the mouth of the forceps to be "out of alignment". This failure was "caused by mishandling/misuse, such as excess force applied to the instrument jaws".[76]

124. Tips of instrument grips were broken. "This failure is most commonly caused by mishandling/misuse, such as excess force applied to the instrument grips".[77]

125. The instrument was found to have a "severely bent grip". This failure is "most commonly caused by mishandling/misuse, such as excess force applied to the instrument jaws". The instrument had 3 uses remaining.[78]

c. Scissor failure:

126. One of the scissor blades on the EndoWrist was indented, preventing the blades from closing. The instrument had 10 uses left. This failure is "most commonly caused by mishandling/misuse".[79]

127. The blade edges on the Potts scissors were indented, preventing the blades from closing. The instrument had 2 uses left. This failure is "most commonly caused by mishandling/misuse".[80]

128. The monopolar curved scissors were found to have blade damage in the form of mechanical indentations on one of the blade edges. This prevented the "blades from

[76] Intuitive-00695006, Tab 1, Row 41874.

[77] Id. at Tab 1, Row 71189.

[78] Id. at Tab 1, Row 47663.

[79] Id. at Tab 1, Row 77102.

[80] Id. at Tab 1, Row 127428.

closing" and is "most commonly caused by mishandling/misuse". The instrument has 3 uses remaining.[81]

d. Unintuitive motion:

129. The needle driver was "found to have an input disk broken" and "completely detached from the base of the housing". The most common cause of this failure is "improper cleaning during reprocessing" such as "prolonged exposure of instrument to harsh cleaning agents". As a result, "the instrument was non-intuitive". The instrument had 3 uses remaining.[82]

130. The prograsp forceps were "found to have contamination at the clamping pulley, causing the grip movement to be stiff". This didn't allow the forcep tips to open enough for "proper tissue handling". The surgical tech replaced the instrument with another one in order for the procedure to continue. The known common cause of this failure is "due to mishandling/misuse". The instrument had 3 uses remaining.[83]

131. The monopolar curved scissors were "found to have the tube extension mating keys damaged". This failure is commonly caused by "hyper-rotating the proximal clevis relative to the tube extension". Moreover, "signs of corrosion were found on the instrument bearings", most commonly caused by "improper cleaning during reprocessing". The instrument had 3 uses remaining.[84]

132. That misuse, mishandling, or improper cleaning can occur at any time, including before an instrument's use counter reaches zero. For example, during my visit to the

[81] Intuitive-00695006, Row 42737.

[82] Id. at Tab 1, Row 70097.

[83] Id. at Tab 1, Row 57332.

[84] Id. at Tab 1, Row 76027.

Rebotix facility, I saw numerous instruments that had experienced a failure prior to their use counter expiring. Those failures included snapped tool ends, fully cut cables, and broken instrument shafts.

b) None of those failures are reflected in the use counter and may occur at any time.

133. An instrument's use counter does not take these failures into account or track whether those failures have occurred. An instrument can have five or six remaining uses, but misuse can cause broken scissors, bent graspers, or broken cables. The only way to accurately determine whether an instrument has been misused or mishandled is through visual inspection or testing. The use counter does not in any other way ensure that an instrument will not be subject to mishandling or misuse.

D. Intuitive's life testing is designed to validate an arbitrarily set use limit set by marketing, rather than to establish the failure point of an instrument.

a) To accurately establish a use limit or failure point, tests would need to actually test instruments to failure.

In my experience studying the failures experienced by mechanical components and medical instruments, testing instruments to failure and observing at which points those failures occur helps to establish the potential range of life for an instrument. Establishing the potential failure modes accurately is important and highly relevant.[85]

134. As an example, in a sample of ten tested instruments, testing each to failure would involve setting certain failure conditions (such as breaks in instrument cables or dulled

[85] *See, e.g.*, "Engineering Failure Analysis, Fatigue & Mechanical Tests: DNV Labs." *DNV*, www.dnv.com/oilgas/laboratories-test-sites/engineering-failure-analysis-fatigue-tests-and-mechanical-tests-dnvgl-labs-hovik html., and "Failure Analysis Testing: Engineering Failure Analysis |." *Stress Engineering Services, Inc*, 14 Feb. 2020, www.stress.com/capabilities/materials-engineering/failure-analysis/.

scissors) and observing at which point each of the instruments experiences a failure. In that ten-instrument sample, one instrument might fail at use 50, and nine others might fail after use 200.

135. By contrast, halting tests after a certain number of uses produces skewed results. In the above example, if testing for the nine other instruments were arbitrarily halted at use 60, the results of the testing would indicate that the instruments had a lower acceptable life. Testing to failure produces an accurate statistical analysis of instrument failures because it actually establishes the range of failure conditions and the useful life of an instrument.

b) Intuitive's testing is designed to validate target lives set by marketing. This does not accurately assess the instrument's failure point.

136. Intuitive's life testing does not accurately assess the useful life of an instrument. Instead of attempting to establish the maximum number of lives that an instrument can be safely used, Intuitive's testing aims to statistically validate a preset target limit.

137. The initial targets for an instrument's use counter are set by marketing.

Page 35
Q. Now, when Intuitive is first considering what it's going to be setting the lives at, marketing is involved in that process; right?
A. Marketing is involved to the extent that they set goals for engineering.
Q. For example, marketing might set a goal of ten lives for an instrument; right?
A. That's an example, yes.
Q. And then engineering would try to design an instrument that would meet that ten-life goal; right?
A. Yes.

-McGrogan depo tr., 35:9-20

Q. But when a new instrument is being

developed for a customer, marketing is setting the target for that instrument before there's any testing that's conducted; right?\

…

THE WITNESS: Marketing sets a goal for reposable instruments.

BY MR. ERWIG:

Q. Then engineering designs and tests an instrument to try to achieve that goal; right?

A. That's right.

-McGrogan depo tr., 64:5-19 (objection omitted)

And the testing performed on an instrument to establish the number of lives on the use counter only takes place after those initial targets have been set by marketing and provided to engineering.

Q. Now, for formal life testing, formal life testing is performed after there's been a particular target set by marketing; right?

A. Typically, yes, formal life testing.

Q. That's ultimately what's used when Intuitive sets the life counter; right?

A. Yes.

-McGrogan depo tr., 65:19-25

138. Intuitive's Weibull Design of Reliability aims to test a sample of instruments to confirm that instruments will reliably meet a pre-set life target.[86] Intuitive deliberately chooses to stop its life testing protocols shortly after the instruments being tested pass the target number of lives. For example, during Intuitive's life testing for extended life instruments, it halted testing instead of testing instruments to failure.[87]

[86] *See, e.g.*, Intuitive-00542459 – Intuitive-00542461.

[87] Intuitive-00642553.

139. The result of this target-based testing approach is that engineers test with those targets in mind and aim to establish reliability for those particular targets. Rather than establishing where failures naturally occur by testing each instrument to failure, the testing process is stopped after passing the target number of instrument lives.

Page 47

Q. Now, telling the lab to stop testing instruments at a certain point, that could involve telling the lab to stop testing instruments once they've reached 17 uses, for example; right?

A. Yes.

Q. Another option would be not to set any stop point for the instruments; right?

A. Yes.

Q. In other words, continuing to test the instruments until they exhibit failure conditions; right?

A. Yes.

Q. In this particular testing, the instruments were stopped at a certain point; right?

A. Yes.

Q. The testing was not performed all the way through to failure; right?

A. Yes.

-McGrogan depo tr., 47:3-20

Page 45

Q. Sure. Marketing might set a target for 15 lives; right?

A. Sure. Yes.

Q. If instruments were tested to failure, then

Page 46

each instrument would be tested until it experienced a failure condition; right?

A. Yes.

Q. And that could happen at 20 uses; right?
A. Yes.
Q. It could happen at 25 uses?
A. Yes.
Q. It could happen maybe even at 30 uses?
A. Yes.

-McGrogan depo tr., 45:22 – 46:9

140. Instruments have passed Intuitive's life testing metrics for higher lives than were actually implemented.

Page 59

Q. Well, there's certainly been instances where the instrument being tested passed more lives than were actually implemented; right?
A. Yes.
Q. Now, the instrument could have been set at a higher number of lives; right?
A. Yes.
MR. RUBY: Object to the form of the question. The witness has answered.

-McGrogan depo tr., 59:9-17

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Q. There's certainly some instances where the number of lives implemented is different from the number of lives proven; right?
A. Yes.
Q. And the number of lives implemented, those are less than the lives proven; right?
A. Yes, in some cases.

-McGrogan depo tr., 62:10-16

141. Those higher life counts were not implemented because marketing's decision to set the usage counter to particular values is driven by maximizing Intuitive's revenue

and profits. As early as 1995, in Intuitive's original business plan, it expected to use instruments as a "major part of [its] recurring revenue."[88] And Intuitive's representatives confirmed that use counters with lower life counts would generate more revenue for Intuitive.

Page 143
6 Q Well, let's assume the same price. If you
7 sell an instrument to a customer that has one use, the
8 customer needs to buy more of those instruments than
9 if an instrument has, let's say, five uses; right?
10 A Yes. And if you set the same price for the
11 one use and five use, then you would see more revenue,
12 maybe not profit, but on one -- one instrument -- on a
13 one-use instrument.
14 Q And if the customer only had the option of
15 buying that one-use instrument, it would be better
16 from a revenue perspective to only design a one-use
17 instrument instead of a five-use instrument; right?
18 A Assuming constant demand and constant volume,
19 from a purely revenue standpoint, not profit, then I
20 think that's a true statement.

-DeSantis depo tr., 143:6-20

142. Intuitive's decision not to re-evaluate the use counter on its Si instruments is a further example of revenue concerns, rather than safety, driving the number of uses that the use counter is set to.

Page 173
2 Q Now, in 2013, if Intuitive wanted to give
3 hospitals the maximum possible number of uses out of
4 every Si instrument, Intuitive could have tested the
5 Si instruments and seen what the appropriate number of

[88] Intuitive-00595682.

uses was as of that time; right?
A That's -- that's one option, yes.
Q Instead Intuitive left the life counter for the Si instruments at ten uses; right?
A Intuitive was investing heavily in a better platform at that time, so we did not choose to invest in the Si instruments to do a life testing and roll out that program. Correct, we did not do that.
Q And so Intuitive left the life counter of the Si instruments at ten uses and didn't try to increase it to 12, 13, or anything else; right?
A Correct.

-DeSantis depo tr., 173:2-17

And even when Intuitive considered an extended lives program for its EndoWrists, revenue considerations were driving its analysis. For example, Intuitive conducted worst case and best case financial impact assessment on the extension of reprocessing cycles for instruments.[89] There is no sign of a best and worst case safety assessment.

E. The use counter fails to independently verify the condition of the instrument. Hospital technicians must do an inspection to ensure that the instrument is safe.

143. The use counter itself does not provide any information about whether an instrument is safe to be used. The use counter does not indicate whether wires are frayed, whether scissors are dulled or broken, or whether there are other errors with the device. The only value on the use counter is how many times the instrument has been used.

144. Rather than relying on the use counter, hospitals examine EndoWrists before surgery to determine whether they are safe for use.[90] When hospital technicians recognize issues with an EndoWrist, it will not be used in surgery.

[89] Intuitive-00624804.

[90] Harrich depo tr., 40:12-25, Donovan depo tr., 33:23-34:9, 35:16-21.

145. Numerous instruments at Rebotix's facility that were received from hospitals were ultimately deemed "Unsuitable for Repair" had remaining uses on the use counter. The instruments I examined with broken cables, for example, each had remaining uses. The use counter alone would not prevent those instruments from being used in surgery.

VII. INTUITIVE'S NEW ENDOWRISTS ARE LESS SAFE THAN REBOTIX'S REPAIRED ENDOWRISTS DUE TO MANUFACTURING ISSUES. BUT INTUITIVE STILL SELLS THOSE INSTRUMENTS, INDICATING THAT RISKS TO PATIENTS ARE ACCEPTABLE.

A. Manufacturing issues can render instruments unsafe.

146. In my experience with medical devices, design testing is only one component of the safety of a device. Manufacturing issues can frequently cause medical devices to fail unexpectedly and in ways not accounted for during design testing. This is evidenced by the creation of the FDA's Good Manufacturing Practices (GMPs) in addition to the extensive pre-market approval process.[91] These GMPs recognize that effective product design is only one step in a long, complex process of bringing a medical device to market.[92] They offer extensive guidelines for manufacturing that extend beyond product design, such as "manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use".[93]

[91] Center for Devices and Radiological Health. "A History of Medical Device Regulation and Oversight in the US." *U.S. Food and Drug Administration*, FDA, www fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states.

[92] Center for Devices and Radiological Health. "Current Good Manufacturing Practice Final Rule; Quality System." *U.S. Food and Drug Administration*, FDA, www fda.gov/medical-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices/medical-devices-current-good-manufacturing-practice-cgmp-final-rule-quality-system-regulation

[93] Id.

a) Manufacturing defects can appear in medical devices in several ways.

147. First, a manufacturing defect may make an instrument immediately unsuitable for use in a manner that can be verified with a visual inspection. For example, an instrument could be missing a key part required for surgery or have unexpected protruding parts.

148. Second, a manufacturing defect may affect the instrument's reliability and cause that instrument to fail earlier than it otherwise would. For example, a defect in a cable manufacturing process could lead to premature cable breaks or derailments. These types of defects are difficult to detect in initial testing.

149. Evidence I have reviewed indicates that Intuitive does not adequately address either of these failures.

B. Intuitive does not adequately address potential manufacturing defects.

a) Intuitive does not appear to have adequate manufacturing quality controls to detect defects that make instruments immediately unsuitable for use.

150. Intuitive has its primary manufacturing facility for EndoWrists in Mexicali, Mexico.[94] Although Dr. Howe extensively discusses the life testing that purportedly ensures that EndoWrists can operate safely for the indicated number of lives, Dr. Howe makes no mention of any testing or quality assurance procedures that are performed to ensure that manufactured EndoWrists comply with these standards.

151. I did not locate any documents in the Intuitive document production to suggest that Intuitive effectively uses manufacturing testing and quality assurance inspections to screen for manufacturing defects. The only produced document relevant to manufacturing testing is an internal Intuitive email chain discussing how to respond to third party "reprogrammers" of

[94] Intuitive-00666937.

EndoWrists, like Rebotix.[95] That email makes general mention of manufacturing testing that "is designed to provide confidence that every instrument is shipped within specifications."[96] But it appears that this unspecified testing fails to detect even basic defects that are visible through visual inspection.

152. I reviewed a video referenced in the deposition of Mr. DeSantis. That video clearly shows a defect in an EndoWrist—a piece of electrical wire is protruding from a monopolar instrument.[97] That defect was recognized by a hospital customer when the instrument was inspected. The defect in the instrument was clearly visible and should have been identified by a simple visual inspection prior to having the instrument shipped to a customer. The apparent lack of a final visual inspection means that new EndoWrists with obvious defects due to manufacturing or assembly problems may be shipped to customers.

153. Mr. DeSantis acknowledged that the instrument in the video was defective, and should be returned to Intuitive by the customer:

Q Can you describe to me what you see is happening in this video?
A So someone is manually manipulating the jaw of the hook, Monopolar instrument. And when they do so, there's a protrusion of the electrical wire.
…
That would be an example of an instrument that would be RMAed by a customer; right?
A It should be, yes.

[95] Intuitive-00194912.

[96] Intuitive-00194916.

[97] DeSantis depo tr., 204:9-14.

-DeSantis depo tr., 205:13-25

Intuitive's RMA data provides additional examples of instruments that were received by customers with manufacturing defects. For example, a customer reported that when the instrument was removed from its packaging, a segment of the conductor wire was sticking out from the yaw pulley. (*See, e.g.*, Intuitive-00695006, Tab 1, Row 56865). As another example, hospitals have reported deformed and distorted scissors prior to use (*See, e.g.*, Intuitive-00695006, Tab 1, Rows 62698, 62713, 62703).

154. Intuitive's approach appears to be to encourage customers to return malfunctioning or failed instruments via the RMA process, rather than addressing the cause of those failures. Indeed, Dr. Howe writes that "Intuitive has identified a variety of instrument failures—within their established usage limits—through the RMA process".[98] Dr. Howe makes not mention of any quality assurance procedures or testing that prevents those issues from occurring in the first instance.

b) Intuitive does not have adequate methods to address defects that may cause instruments to fail earlier than expected.

155. In addition to failing to take into account obvious manufacturing defects before shipping to customers, Intuitive does not adequately address potential manufacturing issues that may affect instrument reliability. Intuitive's decision to ignore manufacturing defects during life testing is illustrative.

156. Dr. Howe repeatedly references Intuitive's life testing conducted on samples of EndoWrists and asserts that this life testing "helps ensure the instruments operate

[98] Howe Report, ¶62.

reliably and safely over their programmed number of instrument uses."[99] But life testing explicitly declines to take manufacturing defects into account by censoring the samples used for life testing. By virtue of this censoring, the test populations are skewed and the test results affected.

157. Instruments selected for testing by Intuitive are frequently "censored" due to manufacturing defects. Censoring of the test population means that EndoWrists with identified manufacturing defects are not considered in the testing analysis. Those censored devices are removed from the life testing by swapping the censored device out for another instrument, or they are not considered in the life testing results. For example, four out of eighteen (22%) test samples for the extended life curved bipolar dissector were "censored due to manufacturing defects."[100]

158. This decision to "censor" instruments that are deemed to have manufacturing defects has significant consequences for the reliability of Intuitive's use counter life setting. It means that manufacturing defects that contribute to early instrument failures are not accounted for in Intuitive's life testing. And it means that as-manufactured EndoWrists sold to hospital customers by Intuitive do not receive the same level of scrutiny and screening during the life testing process.

159. There is no indication that Intuitive conducts other testing or quality assurance inspection on its EndoWrist after manufacture that would identify defects that could cause the instrument to fail before its useful life. Instead, Intuitive relies on the RMA process to deal with these concerns, as discussed above.

[99] Howe Report, ¶57.

[100] Intuitive00552535.

c) Intuitive continues to sell its EndoWrists even though they frequently experience failures

160. Intuitive received approximately 30,000 instruments via RMA in 2019.[101] Those are all instruments that have experienced some sort of failure or complaint prior to the instruments' use counter expiring.[102]

161. Despite Intuitive's knowledge of the tens of thousands of instruments that it receives via RMA, Intuitive continues to sell EndoWrists to hospitals. It does so because in the overwhelming number of instances when an EndoWrist experiences a failure during surgery, that EndoWrist can simply be replaced with a functional model. And it does so because it deems the risks of manufacturing concerns acceptable.

162. RMA instruments suffer a variety of failures, including unintuitive motion,[103] and broken cables.[104] In each of these cited instances, the failure of that instrument occurred during surgery, prior to an instrument having been used for the number of lives specified by Intuitive's use counter. But the procedure was nonetheless completed.

163. Specifically with respect to cable failures, Intuitive performed a risk analysis to determine whether cable failures posed significant patient risks.[105] Intuitive concluded that patient risk even from parts of cables or crimps that might fall into the patient is negligible. This document notes that both cables and crimp are biocompatible and may even be left in a patient if not retrieved during the procedure.[106] Intuitive concludes there is an acceptable and minimal risk

[101] DeSantis depo tr., 202:15-22.

[102] Id. at 203:2-15.

[103] Intuitive-00695006, Tab 1, Row 70097.

[104] Id. at Row 39574.

[105] Intuitive-00536537.

[106] Intuitive-00536541.

to the patient of cable failure or cable fragments even if it should be in the patient for long-term following a procedure.

164. EndoWrists failing before their use counter is up has been confirmed by hospitals. Hospitals report that EndoWrists fail for various reasons including that the teeth on EndoWrists might be misaligned, scissors may be dull, and wires may fray.[107] Hospitals inspect EndoWrists before using them in surgery, and EndoWrists sometimes fail that inspection.[108] That inspection has led to EndoWrists being rejected for various reasons prior to the maximum number of uses specified by Intuitive.[109] When a failure occurs during a surgery, a hospital will remove the EndoWrist from the patient and replace it with another EndoWrist.[110]

165. And in multiple instances, those instruments have even caused injuries to patients during surgery.[111] For example, a Permanent Cautery Spatula "died with three unused uses still on it" during the procedure and, as a result, the patient suffered thermal burns.[112] And a PK Dissecting Forceps malfunctioned during a procedure and caused burns to the patient.[113]

166. Despite all of this RMA data, Intuitive's witness at deposition indicated that there had never been a case where Intuitive adjusted an instrument's life counter downwards due to instruments being received in the RMA process.[114]

[107] Harrich depo tr., 41:15 – 42:5.

[108] Id. at 41:9-11, Donovan 34:20-25.

[109] Id. at 42:21 – 43:3.

[110] Donovan depo tr., 35:25 – 36:3.

[111] *See, e.g.* Intuitive-00695006, Tab 1, Row 123932.

[112] Intuitive-00695006, Tab 1, Row 12308.

[113] Id. at, Tab 1, Row 6121.

[114] Vavoso depo tr., 209:18-23.

C. Rebotix's repair process addresses any manufacturing issues.

167. Unlike Intuitive's decision to consider RMAs of instruments with manufacturing defects acceptable, Rebotix ensures that every instrument that it returns to a hospital is safe and will not injure a patient during surgery.

168. Rebotix's service method and procedure screens out any instruments with serious manufacturing issues. Rebotix's initial inspection verifies that the instrument is performing within its normal operating bounds. Any significant issues with an instrument, like a cable break, a broken tool end, or failed insulation, will result in Rebotix treating the instrument as unsuitable for repair. The instrument in the video identified by Mr. DeSantis above would not have been serviced by Rebotix.

169. Further, after Rebotix repairs an instrument, it ensures that the instrument is fully functional and safe. It tests to ensure that scissors are appropriately sharp,[115] that the instrument is moving intuitively,[116] that the instrument has sufficient grip force,[117] that graspers and drivers are properly aligned,[118] that instrument cables have been precisely tensioned,[119] and that electrical insulation is fully intact and equivalent to a new EndoWrist.[120] It performs a visual inspection that would identify issues like the protruding electrical wire described above.[121] Only after an instrument is repaired, cleaned, and passes this outgoing inspection is it returned to a customer. This approach ensures that every EndoWrist that a customer receives from Rebotix is

[115] REBOTIX133238, REBOTIX133284.

[116] REBOTIX133286.

[117] REBOTIX133282.

[118] REBOTIX133236.

[119] REBOTIX133345.

[120] REBOTIX133253, REBOTIX133302.

[121] REBOTIX133342.

not an EndoWrist that contains manufacturing flaws—those are deemed "Unsuitable for Repair" and not serviced.

VIII. INTUITIVE HAS NO BASIS TO CLAIM THAT ENDOWRISTS REPAIRED BY REBOTIX ARE UNSAFE.

A. To make a claim that EndoWrist repairs are unsafe, one would expect to see general testing of repairs, testing of Rebotix-repaired instruments, or identified issues caused by a repair process.

170. For Intuitive or Dr. Howe to make a claim about the safety of Rebotix's instruments, there would need to be a basis for that claim. One basis might be that Intuitive has conducted its own testing on repairs, and concluded that repairs cannot resolve common failure modes on an instrument. This could lead Intuitive to conclude that repairs by another entity would not be feasible. Another basis could be that Intuitive or Dr. Howe examined instruments repaired by Rebotix, and determined that those instruments raised safety concerns. Alternatively, Intuitive could observe issues in instruments it received from hospitals that suffered failures due to the Rebotix repair procedure.

171. The evidence in this case shows that neither Intuitive nor Dr. Howe has any basis for making claims about Rebotix's instruments being unsafe. Instead, when Intuitive briefly considered offering refurbished instruments, it concluded that those instruments could offer equivalent performance to new instruments.[122]

B. None of Intuitive's extensive testing has examined the feasibility of repairing EndoWrist instruments.

172. Intuitive's life testing process records failures when they occur.[123] But Intuitive never examines whether any of those failures can be repaired. Unlike Rebotix, which

[122] Desantis depo tr., 234:18 - 246:20, Intuitive-00042946, Intuitive-00603241-Intuitive-00603264.

[123] *See, e.g.* Intuitive-00546920.

performed extensive testing on whether EndoWrist instruments could continue to be safely used after the expiration of their initial use counter, Intuitive does not test whether it is possible to repair an instrument when it experiences a failure, even when that failure occurs during the initial usage counter period. For example, when scissors become dull during testing, Intuitive considers that a failure. Intuitive will not attempt to resharpen those scissors and continue testing the instrument.

Page 214
Q Now, in the process of testing, if scissors on a pair of EndoWrist that have scissors at the end
Page 215
become dull and they're no longer cutting, that would be a failure; right?
A Yes.
Q And that could occur at nine uses; right?
A Yes.

…

If an instrument fails because its scissors are dull at, let's say, eight uses, does Intuitive try to resharpen or in any way repair the scissors to determine whether the instrument can last for additional lives?
A No, I don't believe so. We don't typically do repairs as part of our life testing.
Q And so if an instrument failed at, say, eight uses because the scissors were dull, Intuitive would
Page 216
consider that a failure under its life testing; right?
A Yes.
Q Intuitive would log that and store or dispose of the instrument; right?
A Yes.
Q Intuitive would not test whether the instrument could continue to operate to 15 or 20 uses with re-sharpened scissors; right?
A Not if our spec was ten and there was a failure prior to ten, no.

-DeSantis depo tr., 214:24 – 216:10

For every instrument, if there is any type of failure during the life testing process, Intuitive does not attempt any repair or refurbishment of that failure.

Page 216
And that's the same for -- for other types of instruments as well, such as graspers or needle drivers; right? If there's any sort of failure, Intuitive doesn't attempt to repair that failure; right?
A Correct. As part of our life testing remanufacturing, it's not part of our life testing.
Q In fact, any sort of refurbishing repair is not part of life testing; right?
A Correct.

-DeSantis depo tr., 216:12-21

173. For each of the failures that Intuitive experiences in its life testing, it has never attempted repair or refurbishment. Intuitive has never examined whether loose cables can be repaired,[124] whether unintuitive motion can be repaired,[125] whether graspers can be realigned, [126] or whether the grip force on a needle driver can be repaired.[127] Refurbishment is simply not part of Intuitive's life testing process. Additionally, when instruments fail after their target number of uses, Intuitive also does not perform any examination of whether that instrument can be refurbished or repaired to continue to operate safely.

[124] DeSantis depo tr., 272:15-23.

[125] Id. at 277:22 – 278:11.

[126] Id. at 273:2-12; Vavoso depo tr., 235:15-18.

[127] Id. at 276:4-8.

Page 216
22 Q Now, if an instrument -- the desired spec for
23 an instrument is ten uses and the instrument fails at
24 11 uses, Intuitive doesn't also attempt any
25 refurbishment or repair of that instrument at that
Page 217
1 point; right?
2 A Correct.
3 Q So if an instrument, for example, failed at
4 11 uses because the scissors had dulled, Intuitive
5 would not examine whether a repair could let that
6 instrument operate safely; right?
7 A Not typically, no.

-DeSantis depo tr., 216:22 – 217:7

174. Even when Intuitive receives instruments from hospitals that have failed before their use counter has expired, Intuitive does not investigate whether it's possible to repair whatever failure the instrument has experienced.[128] Intuitive simply categorizes those failures as part of its RMA program.[129]

C. Intuitive has not tested any instruments repaired by Rebotix, and has no basis for its assertions about the safety of those instruments.

175. Despite making numerous claims about the safety of Rebotix's instruments to both hospital customers and the FDA, there is no indication that Intuitive has ever actually tested an EndoWrist repaired by Rebotix to evaluate whether it is equivalent to a new EndoWrist.

Page 245
6 Intuitive has not done testing of any kind to
7 determine whether Rebotix's refurbished EndoWrists can

[128] DeSantis depo tr., 144:10-14, 146:3-15.

[129] Intuitive-00695006.

8 safely be used with the da Vinci robot in surgery;
9 true?
10 A True. We've not done V&V testing, life
10 testing on their instruments, no.

-DeSantis depo tr., 245:6-11

As detailed in Dr. Sharlin's report, Intuitive has no support for its assertions that Rebotix's instruments pose risks to patients due to unintuitive motion, insufficient grip force, dull or damaged scissor blades, or worn or damaged cables.[130] This was confirmed by Intuitive's witnesses at deposition:

(1) Unintuitive motion:

18 Q. Are you aware of any investigation or
19 analysis by Intuitive to determine whether Rebotix's
20 services caused EndoWrists to have unintuitive
21 motion?
22 A. I am not aware.

-Johnson depo. tr., 119:18-22.

15 Q. You have no basis to assert that
16 Rebotix is unable to ensure intuitive motion
17 in EndoWrists based on the services it
18 performs, correct?
19 MS. LENT: Object to the form.
20 THE WITNESS: That's correct.

-Curet depo. tr., 151:15-20.

(2) Insufficient grip force:

[130] Sharlin report, ¶¶82 – 92.

Q. Are you aware of any investigation or analysis by Intuitive that Rebotix's services caused EndoWrist to have insufficient grip force?
A. I am not aware.

-Johnson depo tr., 119:23-120:1.

You have no basis to assert that Rebotix is unable to implement measures in its servicing of EndoWrists to ensure that those EndoWrists have sufficient grip force, correct?
MS. LENT: Object to the form --
THE WITNESS: That's correct. That's correct.

-Curet depo. tr., 151:6-13.

(3) Dull or damaged scissor blades:

Q. Are you aware of any investigation or analysis by Intuitive that Rebotix's services result in EndoWrists having dull or damaged scissor blades?
A. Nope, no

-Johnson depo. tr., 120:6-9.

Q. Has Intuitive performed any tests of Rebotix repaired EndoWrist to determine if they had dull or damaged scissor blades?
MS. LENT: Object to the form.
THE WITNESS: I don't know.

-Curet depo. tr. 153:11-15.

Q. You don't have any basis to assert that Rebotix can likewise take measures to ensure that its serviced EndoWrists have sufficiently sharp and nondamaged scissor blade, correct?

MS. LENT: Object to the form.
THE WITNESS: That's correct.
-Curet depo. tr., 153:22-154:3.

(4) worn/damaged cables:

Q. Are you aware of any investigation or analysis that Rebotix's services caused EndoWrists to have worn or damaged cables?
A. I am not aware of that.
-Johnson depo. tr., 120:1-5.

You have no basis to assert that Rebotix does not also take measures to ensure that the cables are not worn, not damaged, and have sufficient tension, correct?
MS. LENT: Object to the form.
THE WITNESS: Correct.
-Curet depo. tr., 163:20-25.

176. Hospitals that used the Rebotix repair services and were informed by Intuitive that those instruments might pose safety risks asked Intuitive to provide data indicating that the instruments repaired by Rebotix were unsafe. Intuitive has never been able to provide any sort of data or test results indicating that Rebotix repaired instruments pose safety concerns.[131]

D. None of the instruments that Intuitive received via the RMA process show issues caused by the Rebotix service process.

177. Dr. Howe asserts that Intuitive has observed instrument "failures" in instruments that have been repaired by Rebotix and returned to Intuitive through the RMA process.[132] Dr. Howe attempts to tie these failures to "wear and tear" or improper servicing by Rebotix. But the underlying data that Dr. Howe references shows that the failure modes on these

[131] DeSantis depo. tr., 270:7-10.

[132] Howe Report, ¶64.

instruments was not related to Rebotix repair procedures. In fact, the majority of the instruments referenced experienced failures due to damage and misuse during the cleaning process.

178. In the Excel spreadsheet Dr. Howe references, there are descriptions of the errors observed in EndoWrists that have had their lives extended.[133] Dr. Howe cites to several of the entries in that spreadsheet to highlight purported "failures" on instruments repaired by Rebotix. Intuitive was able to detect instruments that had been repaired by Rebotix by inspecting for the Interceptor board. But a careful examination of the description of failures on those instruments reveals that the failures were not caused by the Rebotix repair process, that the instruments were functional, and that the failures did not in any instance prevent a surgery from being completed. Most importantly, there has been no indication that an instrument serviced by Rebotix Repair has caused any patient injury or harm.

a) Failures not caused by Rebotix

179. Failures in instruments that have had their useful lives extended were not caused by Rebotix repair procedures. Several of the instruments were found to have experienced a failure due to "improper cleaning."[134] Intuitive concluded that for those failures, "improper cleaning during reprocessing most commonly causes this,"[135] and there was no indication that Rebotix's services in any way caused these failures. And for the instruments that had "broken cables" as a listed failure, Intuitive concluded that "[t]his failure is most commonly caused by mishandling/misuse, such as excess force applied to the distal end of the instrument."[136] Excess force or misuse can occur at every stage of an instrument's life, including within the first ten uses.

[133] Intuitive-00695006 at Tab 2.

[134] Id. at Row 17, 18, 24.

[135] Id. at Tab 2, Row 24.

[136] *See, e.g.,* Id. at Tab 2, Row 28, 29, 30, Column AB.

Moreover, none of the instrument cause of failure notes in the spreadsheet actually indicate that any of the instrument failures were as a result of the Rebotix service procedure.

b) Instruments remained functional

180. Several of the other instruments had no functional issues when inspected by Intuitive. For example, four instruments cited by Dr. Howe were classified as having experienced failures because the da Vinci robot "failed to recognize" the EndoWrist.[137] The accompanying description for each of these EndoWrists shows that there was no indication that anything else was wrong with the instrument. They also showed no sign that the failure to recognize the EndoWrist was due to Rebotix's service procedure. Indeed, Intuitive's new, EndoWrists can fail to be recognized by the da Vinci robot.[138]

181. And Intuitive was often unable to replicate the customer's concerns. For example, Row 17 contains an instrument that was actually tested in an attempt to replicate customer concerns. In its testing, Intuitive was unable to replicate the concerns expressed by the customer. The instrument was attached to the Si system, no error messages or faults appeared, the pins did not stick and were not contaminated, and the EndoWrist was driven and moved intuitively.[139]

c) In cases where failures occurred during surgery, each surgery was completed successfully with no adverse effect on the patient

182. The spreadsheet Dr. Howe references contains 24 instruments in the United States that had their useful lives extended before being returned to Intuitive through the RMA

[137] Id. at Tab 2, Rows 15, 17, 44, 47.

[138] *See, e.g.*, Intuitive-00695006, Tab 1, 15506, 60952, 68890, 70768, 131231

[139] Intuitive-00695006, Tab 2, Row 17.

process. Of those instruments, 7 experienced some sort of issue during the procedure. And each one of those procedures was completed successfully with no patient injury or adverse event.[140]

d) There has been no indication that the use of any instrument serviced by Rebotix Repair has caused any patient harm.

183. Since Rebotix Repair began offering its services in the United States in 2019, I have seen no evidence or indication that the instruments repaired by Rebotix have caused any adverse event or resulted in any patient harm. Dr. Howe does not identify any such evidence, or argue otherwise in his report.

E. When Intuitive briefly considered developing refurbished EndoWrists, it did not conclude that refurbished EndoWrists would be unsafe. Rather, Intuitive chose not to pursue refurbishment because that program would not be profitable for Intuitive.

184. Intuitive considered a program to refurbish EndoWrists in 2017.

2 I understand that in 2017 Intuitive
3 considered refurbishing EndoWrists; is that right?
4 A Yes.

-DeSantis depo tr., 227:2-4

Those refurbished instruments would have equivalent performance to new instruments, and would have the same use counter as new instruments.

Page 236
5 Q Under "Clinical Performance," the first
6 bullet point reads "Equivalent performance" right?
7 A Yes.
8 Q Do you understand that to mean refurbished
9 instruments would have new equivalent performance to
10 new EndoWrist?
11 A Yes. We wouldn't release instruments to the
12 field that had inferior performance than our specs.
13 Q And the second bullet point is:

[140] Intuitive-00695006, Tab 2, Rows 28, 29, 30, 31, 44, 45, 46.

"10 lives per instrument."
Right?
A Yes.
Q That would mean the refurbished instruments would have a 10-life use counter on them as well; right?
A Yes, according to the slide.

-DeSantis depo tr., 236:5-20

And Intuitive concluded that refurbished instruments could provide equivalent performance to new instruments.

Page 237
Q As of April 11, 2017, was it yourss understanding that refurbished instruments could provide equivalent performance to new instruments?
A Yes.

-DeSantis depo tr., 237:16-19

185. Intuitive ultimately made the decision not to pursue an instrument refurbishment program because the program would not be profitable for Intuitive. There was no conclusion that the instruments would not be suitable for refurbishment.

Page 266
Now, ultimately Intuitive did not pursue an instrument refurbishment program for the da Vinci Si or for the da Vinci Xi; right?
A Not to date.
Q It's because instrument refurbishing, that's something that's not profitable for Intuitive; right?
A Yeah. Financially it turned out to be essentially a wash between building new instruments and going through the entire process of collecting and

> 10 remanufacturing to original specs, et cetera.
>
> -DeSantis depo tr., 266:1-10

IX. DR. HOWE SIMILARLY DOES NOT HAVE ANY BASIS FOR ASSERTING THAT INSTRUMENTS REPAIRED BY REBOTIX ARE UNSAFE.

A. Appropriate conclusions about the safety of an instrument can be drawn from an examination of the instrument or an examination of all relevant information about how the instrument is serviced.

186. In my experience as a mechanical engineer, I have previously assessed potential safety concerns with service procedures or instrument repair processes. In performing this analysis, I will either directly examine the repaired device in question and the accompanying service process, or I will consider the entire documentation that details the service procedure.

187. Dr. Howe took neither approach. Instead, Dr. Howe attempted to draw conclusions about the safety and reliability of the Rebotix repair process from a general document (the EndoWrist Service Procedure) and a single video of a repair procedure being performed.[141] Dr. Howe used these sources to conclude that "significant problems exist with Rebotix's approach" to repairing EndoWrists.[142]

188. There are two problems with this evaluation of the Rebotix procedures by Dr. Howe. First, Dr. Howe has never examined nor tested an EndoWrist repaired by Rebotix. Second, Dr. Howe did not consider or examine the underlying, detailed procedure documents that provide additional detail about the Rebotix repair process.

[141] Howe Report, ¶68.

[142] Id. at ¶67.

B. Dr. Howe has no experience with EndoWrists repaired by Rebotix.

189. Just like Intuitive, Dr. Howe has never done any testing on Rebotix-repaired EndoWrists. Dr. Howe has not compared a Rebotix-repaired EndoWrist to a new instrument, has not inspected a Rebotix-repaired EndoWrist for cable wear, and has not examined the current practices of Rebotix in repairing its instruments.

190. Instead, Dr. Howe engages in speculation about potential safety concerns, while ignoring relevant fact and testimony in the case. For example, Dr. Howe makes speculative claims about the number of failures suffered by Rebotix's instruments on the basis of the total instruments sold by Rebotix.[143] But Dr. Howe never considers testimony by hospital representatives that EndoWrists repaired by Rebotix function identically to new Intuitive EndoWrists, and that they have not suffered failures.[144]

191. Dr. Howe's lack of experience with Rebotix instruments is reflected in his misunderstanding of various aspects of Rebotix's repair process. For example, Dr. Howe asserts that "particulate debris" is generated by Rebotix's methods and that "only inadequate methods are suggested" for dealing with that particulate debris.[145]

[143] *See, e.g.,* Footnote 110, "While I do not have complete information on the number of failures that occurred among EndoWrist instruments that had usage lives extended by Rebotix, I would expect the actual number of failures to be higher".

[144] Harrich depo tr., 38:9-39:9, Harrich depo tr., 40:2-8, Harrich depo tr., 43:2-19.

[145] Howe Report, ¶74.

192. Dr. Howe identifies that "blowing on the instrument" and "brushing the instrument" are not adequate means to effectively remove debris.[146] But Dr. Howe does not consider the extensive cleaning process that occurs before the instrument is shipped back to the hospital. That process is detailed in the cleaning and sterilization protocols that are present at the technician's station.

Photograph taken at Rebotix facilities on August 10, 2021.

193. The cleaning and reprocessing steps include an ultrasonic cleaning, flushing of the instrument tubes, drying, lubrication, and disinfection. And even though Rebotix does not return the instrument to the hospital sterile, it nonetheless sterilizes the instrument to ensure that

[146] Howe Report, ¶74.

there are no contaminants prior to shipment. This process of cleaning prior to shipping the instrument back to the hospital also resolves any concerns with the "shop air" that Dr. Howe claims may introduce contamination to the instrument.[147]

C. Dr. Howe only points to the general Rebotix service description, but ignores all of the underlying documents that are referenced.

a) Rebotix has general service documents that reference underlying documentation for more specificity.

194. The complete set of Rebotix service procedures are not contained in a single document. Instead, details about the individual steps in a service procedure are contained in a number of underlying documents. These documents are frequently cross-referenced. As one example, a Rebotix document that describes the final testing of EndoWrists prior to being shipped back to the customer provides a general description of the testing process.[148] That document then references a number of underlying documents that provide more detail about the underlying steps.

6.0	Perform Degree of Freedom test per SOP PR3039.
7.0	Perform Cutting Efficiency Test per SOP PR3038 (Models with scissors or blades only)
8.0	Perform Gripping Efficiency Test per SOP PR3037 (Grasper and Needle Driver Models only).
9.0	Perform Hipot Test per SOP PR 3041.
10.0	Perform DC Resistance Test per SOP PR3042. Monopolar, Bipolar and PK units only
11.0	Perform device recognition test per SOP PR3008. Verify that Lot / Serial # on screen matches the traveler and housing. Verify that the device make and number of remaining uses is correct.

REBOTIX123448

195. A technician seeking to perform a "Degree of Freedom" test would reference the document SOP PR3039. And that document provides extensive additional detail on how to test the various EndoWrist degrees of freedom. For example:

[147] Howe Report, ¶80.

[148] REBOTIX123448.

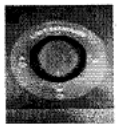
5.0 PROCEDURE:

5.1 Setup

5.1.1 Turn on the Optical Comparator using the green rocker switch located near the base.

5.1.2 Turn on the QM-Data 200 using the green illuminated switch on the back of the unit.

5.1.3 Make sure the Light Exchanger dial is in the center position (profile and surface illumination).



5.1.4 Before first EndoWrist measurement of the day, refer to WI3039 to perform a measurement verification of the Optical Comparator and QM-Data 200 using a calibrated angle block.

5.1.5 With the green shaft clamp open and the wheel manipulation plate off, load the EndoWrist into the fixture upside down. Make sure the EndoWrist tabs on the main body mate properly and are fully engaged so that all rotation wheels are completely visible.

5.1.6 Place PR1151-004 Disc Isolator Plate 4 onto the EndoWrist.

5.1.7 Use the large grey dial to raise or lower the comparator table and fixture until the EndoWrist shaft is centered in the viewer.

5.1.8 Use the release tabs and the black dial on the right side of the table to center the tool end of the EndoWrist in the viewer.

5.1.9 Use the black dial on the left side of the table to focus the image in the viewer.

5.2 Measure Pitch 3 Degree of Freedom.

5.2.1 Ensure that Rotation Wheel 4 is in Neutral Position and lock down green clamp onto shaft.

5.2.2 Center the Image crosshairs on the Wrist Clevis Pin.
5.2.3 Using the QM Data or the Overlay, ensure that the Tool Clevis is at 0° +/- 5°.
5.2.4 Remove Disc Isolator Plate 4.
5.2.5 Manipulate Wheel 3 by hand and ensure that the Tool Clevis travels the full Degree of Freedom until its mechanical stops of the Wrist Clevis without any clicking, snagging, or artificial stops.

5.3 Measure Yaw 1 & 2 Degree of Freedom.
5.3.1 Release the green clamp and rotate the shaft 90°. Lock the green clamp back onto the shaft.
5.3.2 Place Disc Isolator Plate 4 back onto EndoWrist Wheels.
5.3.3 Center the Image Crosshairs on the Tool Clevis Pin.
5.3.4 Using the QM Data or the Overlay, ensure that the Tool End of the EndoWrist is at 0° +/- 5°.
5.3.5 Remove Disc Isolator Plate.
5.3.6 Manipulate Wheel 1and 2 by hand and ensure that the Tool End of the device travels the full Degree of Freedom until it reaches the Tool Clevis mechanical stops without any clicking, snagging, or artificial stops.

5.4 Complete applicable paperwork and refer to PR3048 Process Flow Chart.

REBOTIX134750-REBOTIX134754

196. Similarly, a technician performing the "Hipot Test" described in step 9.0 would reference the detailed instructions in PR 3041 Dielectric Testing SOP.

5.0 PROCEDURE:

5.1 Monopolar Cautery EndoWrist Dielectric Testing Procedure.

5.1.1 Turn On Hipot Tester.

5.1.2 Configure the Hipot testing to the parameters listed in Table 1. Note: These parameters can be stored into memory for quick recall.

Test Type	ACW
Voltage	2.83kV
Max Lmt	2.00mA
Min Lmt	0.010mA
Ramp UP	0.1s
Dwell	30.0s
Ramp DN	0.0s
Arc Sense	0
Frequency	60Hz
Continuity	OFF
Max Lmt	1.00Ω
Min Lmt	0.00Ω
Offset	0.00Ω
Connect	OFF

Table 1 ***Hipot Tester Settings for Monopolar Cautery EndoWrist***

5.1.3 Place the EndoWrist into the PR1107 Hipot Test Fixture. Configure the Hipot Test Fixture to accommodate the EndoWrist under Test, using the front spacer for reference #'s 420183 and 420184.

Page 1 of 5

5.1.4 Clamp the top of Hipot Tester down so that the shaft is securely in place in the Hipot tester.
5.1.5 Connect the black lead from the Hipot tester to the metal stud on the top of the Hipot Test Fixture.
5.1.6 Connect the red lead from the Hipot tester to the Monopolar connection on the back of the EndoWrist.
5.1.7 Activate the Hipot tester by pressing the Green button on the front of the Hipot Tester. Use care not to touch the device during testing, a shock could result.
5.1.8 The device will be tested for a period of 30sec. If at any point during the testing, a breakdown occurs, the Hipot Tester will alarm.
5.1.9 If the EndoWrist under test passes, the Hipot tester will indicate pass.
5.1.10 Remove the EndoWrist from the Hipot Test Fixture.

REBOTIX134655-134656

Each of the other steps in Rebotix's process has similarly detailed descriptions that detail how to perform the steps in Rebotix's service procedure.

b) Dr. Howe consistently ignores these underlying procedure documents when he makes generalized assertions about Rebotix's service procedures.

197. Dr. Howe did not consider all of the Rebotix service materials that he could have consulted. This resulted in Dr. Howe misunderstanding and mischaracterizing aspects of Rebotix's repair process. For example, Dr. Howe asserts that Rebotix does not take steps to guard against inadequate holding force on the PCB mounting clips.[149] But this risk is expressly accounted for in Section 6.5.11 in the Rebotix service process.[150] In addition, Rebotix adds a screw near the flex board that provides for additional mechanical fixation of the Interceptor assembly.[151]

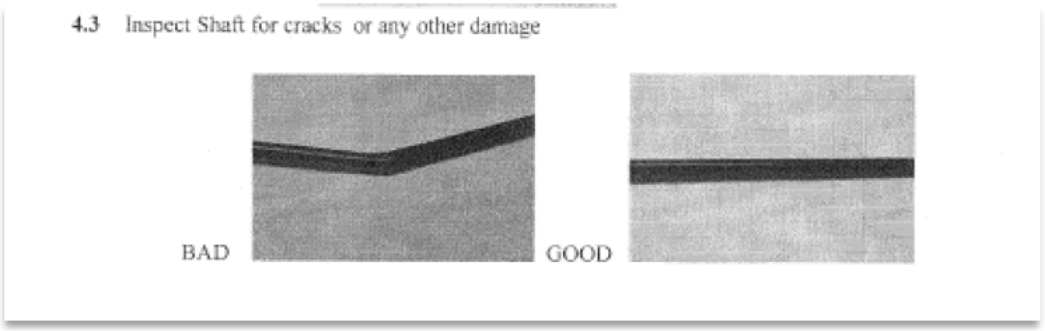
[149] Howe Report, ¶75.

[150] "Verify the PCB is held firmly in place, and does not move when the pins are pressed on." REBOTIX162444.

[151] REBOTIX160706.

REBOTIX170136

198. As a second example, Dr. Howe asserts that Rebotix does not check for "damage to the instrument main tube."[152] However, Rebotix's service procedure for evaluating incoming EndoWrists (PR3043) clearly informs technicians to "inspect [EndoWrist] Shaft for cracks or any other damage."[153]



REBOTIX121303

[152] Howe Report, ¶79.

[153] REBOTIX121303.

199. The inspection includes both external mechanical damage, and electrical tests that can detect any damage to the integrity of the main instrument tube.

200. As a third example, when Dr. Howe asserts that "Rebotix's instructions are unclear and incomplete," he claims that the instructions for testing scissor sharpening do not specify what TheraBand material is or how it is to be used.[154] TheraBand material is made of rubber latex and is used by Rebotix to test and assess the cutting ability of EndoWrist scissors. Rebotix specifies the TheraBand material—it is a particular type of TheraBand material ordered only from a specific approved manufacturer.[155] And Rebotix inspects the TheraBand material before using it in testing the cutting capability of sharpened scissors.[156]

201. Further, Rebotix's "PR3038 Testing the Cutting Efficiency of EndoWrist Scissors SOP" clearly specifies how the TheraBand material is used in the sharpening and testing process:

[154] Howe Report, ¶81.

[155] REBOTIX153047.

[156] Id.

TITLE: PR3038 Testing the Cutting Efficiency of EndoWrist Scissors SOP

1.0 PURPOSE:
This document provides the procedure for testing the cutting efficiency of DaVinci EndoWrists.

2.0 SCOPE:
This procedure applies to DaVinci EndoWrist Scissors.

3.0 APPLICABLE DOCUMENTS:
- **3.1** DIN 58298
- **3.2** PR3047 Test Form
- **3.3** PR3048 Process Flow Chart

4.0 PROCEDURE:
- **4.1** Inspect the blades under 10X magnification:
  - **4.1.1** There should be no defects present on the cutting surface of the blades or the entire blade assembly. The cutting edge should be sharp and burr free.
  - **4.1.2** Like parts must be symmetrical in size and shape.
- **4.2** Using PR1138-002 TheraBand control material, make 3 continuous cuts across 2/3 of the cutting length of the scissors, without exerting any lateral pressure:
  - **4.2.1** It must be possible to separate the test material smoothly, and without it slipping or snagging on the blades.
  - **4.2.2** The scissors should not stick while cutting.
- **4.3** Complete applicable paperwork and refer to PR3048 Process Flow Chart.

REBOTIX134642

Dr. Howe failed to consider any of these underlying documents in assessing the safety of Rebotix's repair process.

X. SPECIFIC PARAGRAPH BY PARAGRAPH RESPONSES TO DR. HOWE

A. Issues Dr. Howe identifies with service process

a) Particulate contamination from steps in repair process (¶¶74 – 76)

202. Rebotix ultrasonically cleans the EndoWrist to ensure that any debris generated during the repair process is removed.[157] It performs this part of its repair process before an instrument is returned to the hospital.

203. As discussed above and as I observed in my visit, this process of cleaning would resolve any hypothetical particulate contamination that Dr. Howe speculates might result from various parts of the Rebotix service procedure.

[157] REBOTIX162422, 6.4.4.

b) Cable Tensioning (¶¶77 – 79)

204. Dr. Howe asserts that Rebotix's process for cable tensioning is inadequate.[158] I disagree with his assertion. The purpose of cable tensioning is to avoid the results of a cable being too tight or too slack. When a cable is too tight, the wheels on the bottom of the EndoWrist require additional torque to move the cables, resulting in unintuitive or rough motion. Similarly, when a cable is too slack, the EndoWrist cable system does not accurately transmit the motions from the surgeon console to the end of the EndoWrist instrument, resulting in unintuitive motion. The only reason for identifying a specified tension number for the cable is that the tension value generally correlates to a device that is not exhibiting the results of being too slack or too tight. But it is the condition of the cable that matters, not the number itself. Adjusting to a number is only a sign that the tension is likely correct; it does not assure that the too tight or too slack conditions are not occurring. The only way to determine whether too tight or too slack conditions are occurring is to directly test for those conditions on each device. And that is what Rebotix does.

205. Rebotix's process is superior to adjusting a torque wrench to a specific number, which only approximates the end goal, because Rebotix directly tests the result of the cable tension to see that the conditions that would result from the cable being too tight or too slack are not present.

206. Moreover, Rebotix confirmed that its cable tensioning procedures were appropriate during its extensive testing of the EndoWrist. In its original testing, Rebotix determined the desired torque values for the mechanical wheels at the bottom of the EndoWrist, and quantified each of those values. Rebotix's life testing protocols established calibration of the instrument's torque, and specified the range of motion of each EndoWrist wheel. In the image

[158] Howe Report, ¶77.

below, Rebotix discusses calibration for each mechanical wheel on the EndoWrist (identifying specific values), and describes the mechanical degree of freedom expected of the jaws of the device.

REBOTIX170067

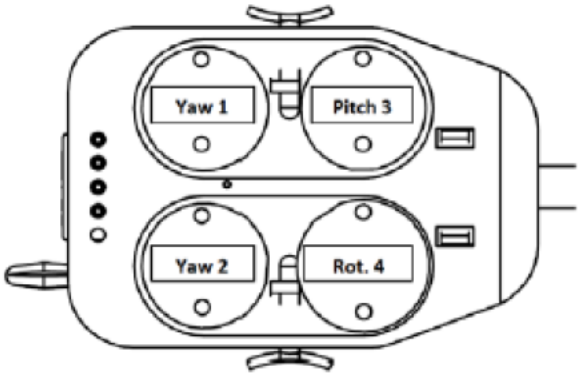


Figure 1

mechanical_wheel_no_load_torque_yaw_2

The no load torque of the Yaw 2 wheel shall be calibrated to 3.0 – 7.0 in. oz f. of torque. (Clockwise and counterclockwise wheel rotation). Refer to figure 1 for identification of the Yaw 2 wheel.

mechanical_wheel_no_load_torque_pitch_3

The no load torque of the Pitch 3 wheel shall be calibrated to 3.0-6.8 in. oz f. of torque in the clockwise wheel rotation. The no load torque of the Pitch 3 wheel shall be calibrated to 4.2-10.7 in. oz f. of torque in the counter-clockwise wheel rotation. Refer to figure 1 for identification of the Pitch 3 wheel.

mechanical_wheel_no_load_torque_rotation_4

The no load torque of the Rotation 4 wheel shall be calibrated to .25-2.0 in. oz f. of torque. (Clockwise and counterclockwise wheel rotation). Refer to figure 1 for identification of the Rotation 4 wheel.

mechanical_degree of freedom_yaw

The jaws of the device shall move freely (without binding or slipping) in the Yaw directions (clockwise and counter-clockwise) to the tool clevis mechanical stops (See Figure 2) when the Yaw 1 and Yaw 2 wheels are rotated in both directions.

207. The PR3052 Spool Torque SOP shows the different torque values specific to each EndoWrist's clockwise and counter-clockwise wheel movement.

Ref	EndoWrist	Yaw 1 in. oz f.		Yaw 2 in. oz f.		Pitch 3 in. oz f.		Rotation 4
		Clockwise	Counter Clockwise	Clockwise	Counter Clockwise	Clockwise	Counter Clockwise	Both Ways
420001	Potts Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420006	Large Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420007	Round Tip Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420036	Debakey Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420048	Long Tip Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420049	Cadiere Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420093	ProGrasp Forceps	2.0 - 4.6	2.4 - 5.6	2.0 - 4.0	2.6 - 5.0	2.0 - 6.5	4.3 – 9.7	.25 – 2.0
420110	Precise Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420171	Micro Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420172	Maryland Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420178	Curved Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420179	Monopolar Curved Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420181	Resano Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420183	Permanent Cautery Hook	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420184	Permanent Cautery Spatula	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	.25 – 2.0
420189	Double Fenestrated Graspers	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	.25 – 2.0
420190	Cobra Grasper	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420194	Mega Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420205	Fenestrated Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420207	Tenaculum Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420227	PK Dissecting Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420296	Large SutureCut Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420309	Mega SutureCut Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420344	Curved Bipolar Dissector	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0

Table 1

REBOTIX133349

208. As part of that testing of wheel torque values, Rebotix examined the cable tension that is required to achieve the desired intuitive motion of each EndoWrist. And Rebotix concluded that when it tightened the cables enough to remove the slack from the cables, the wheel

torque values were in an acceptable range, and more importantly, its repaired EndoWrists functioned equivalently to new EndoWrists sold by Intuitive.[159]

209. Rebotix then tested wheel torque values over multiple uses to determine whether those values were altered by any cable tension issues. For example, in the second round of life testing (life testing performed on instruments that had already been repaired by Rebotix once), Rebotix measured wheel torque values on each of the tested EndoWrists to ensure that they were within an acceptable range after an additional eleven uses. And the wheel torque values exhibited what Rebotix also verified during its manual testing: the instrument cables performed their function and each EndoWrist moved intuitively.

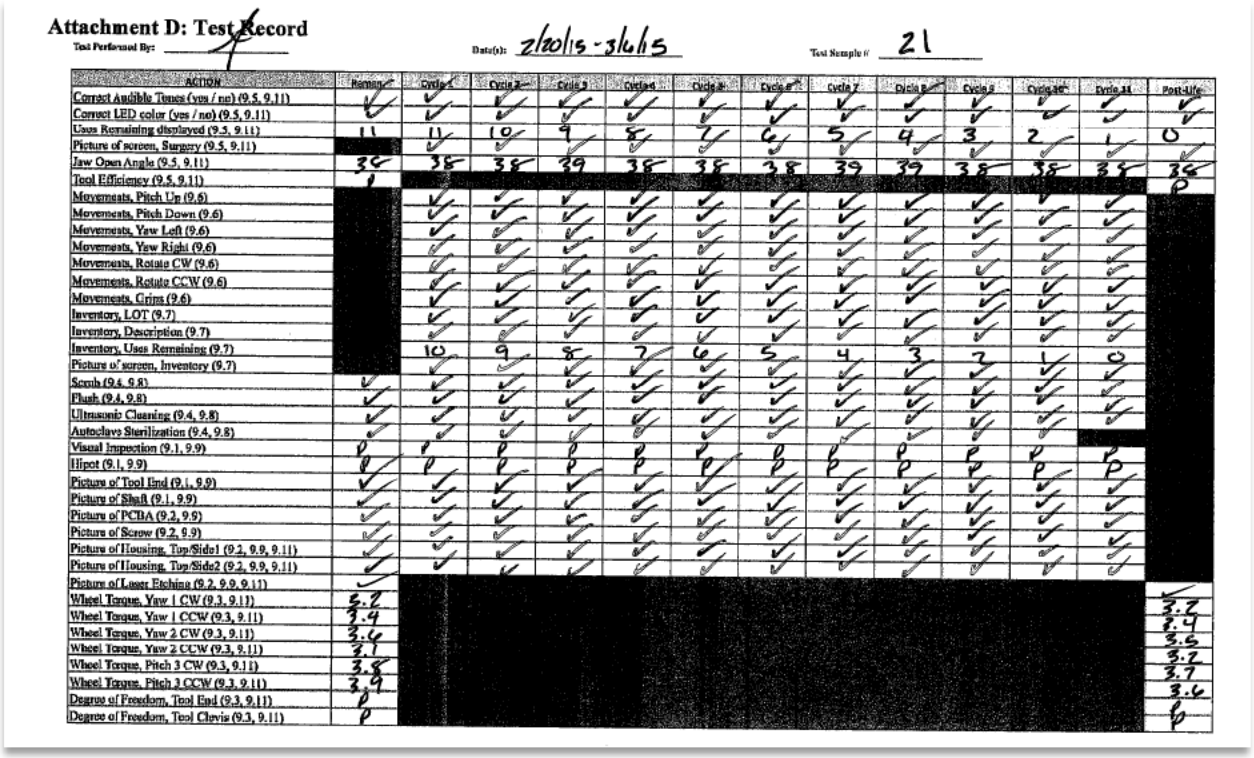
Attachment D: Test Record

Test Performed By: [illegible] Date(s): 2/20/15 - 3/6/15 Test Sample #: 22

ACTION	Repair	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10	Cycle 11	Post-Life
Correct Audible Tones (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Correct LED color (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Uses Remaining displayed (9.5, 9.11)	11	11	10	9	8	7	6	5	4	3	2	1	0
Picture of screen, Surgery (9.5, 9.11)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Jaw Open Angle (9.5, 9.11)	38	38	38	38	38	38	38	38	38	38	38	38	38
Tool Efficiency (9.5, 9.11)	P												P
Movements, Pitch Up (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Pitch Down (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Left (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Right (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CCW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Grips (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, LOT (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Description (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Uses Remaining (9.7)		10	9	8	7	6	5	4	3	2	1	0	
Picture of screen, Inventory (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Scrub (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Flush (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Ultrasonic Cleaning (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Autoclave Sterilization (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Visual Inspection (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Hipot (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Picture of Tool End (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Shaft (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of PCBA (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Screw (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side1 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side2 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Laser Etchings (9.2, 9.9, 9.11)	✓												—
Wheel Torque, Yaw 1 CW (9.3, 9.11)	3.7												3.5
Wheel Torque, Yaw 1 CCW (9.3, 9.11)	3.6												3.3
Wheel Torque, Yaw 2 CW (9.3, 9.11)	3.4												3.4
Wheel Torque, Yaw 2 CCW (9.3, 9.11)	3.4												3.3
Wheel Torque, Pitch 3 CW (9.3, 9.11)	3.3												3.1
Wheel Torque, Pitch 3 CCW (9.3, 9.11)	3.4												3.5
Degree of Freedom, Tool End (9.3, 9.11)	P												P
Degree of Freedom, Tool Clevis (9.3, 9.11)	P												P

REBOTIX132562

[159] Fiegel conversation, *see also* REBOTIX124900-REBOTIX124923, REBOTIX120686.



Attachment D: Test Record

Test Performed By: _____ Date(s): 2/20/15 - 3/6/15 Test Sample #: 21

ACTION	Remain	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10	Cycle 11	Post-Life
Correct Audible Tones (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Correct LED color (yes / no) (9.5, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Uses Remaining displayed (9.5, 9.11)	11	11	10	9	8	7	6	5	4	3	2	1	0
Picture of screen, Surgery (9.5, 9.11)	[redacted]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Jaw Open Angle (9.5, 9.11)	36	38	38	39	38	38	38	39	39	38	38	38	36
Tool Efficiency (9.5, 9.11)	1	[redacted]											P
Movements, Pitch Up (9.6)	[redacted]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	[redacted]
Movements, Pitch Down (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Left (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Yaw Right (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Rotate CCW (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Movements, Grips (9.6)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, LOT (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Description (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Inventory, Uses Remaining (9.7)		10	9	8	7	6	5	4	3	2	1	0	
Picture of screen, Inventory (9.7)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Scrub (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Flush (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Ultrasonic Cleaning (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Autoclave Sterilization (9.4, 9.8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Visual Inspection (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Hipot (9.1, 9.9)	P	P	P	P	P	P	P	P	P	P	P	P	
Picture of Tool End (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Shaft (9.1, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of PCBA (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Screw (9.2, 9.9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side1 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Housing, Top/Side2 (9.2, 9.9, 9.11)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Picture of Laser Etching (9.2, 9.9, 9.11)	✓	[redacted]											✓
Wheel Torque, Yaw 1 CW (9.3, 9.11)	3.7												3.7
Wheel Torque, Yaw 1 CCW (9.3, 9.11)	3.4												3.4
Wheel Torque, Yaw 2 CW (9.3, 9.11)	3.6												3.6
Wheel Torque, Yaw 2 CCW (9.3, 9.11)	3.7												3.7
Wheel Torque, Pitch 3 CW (9.3, 9.11)	3.8												3.7
Wheel Torque, Pitch 3 CCW (9.3, 9.11)	3.9												3.6
Degree of Freedom, Tool End (9.3, 9.11)	P												P
Degree of Freedom, Tool Clevis (9.3, 9.11)	P												P

REBOTIX132559

c) Visual inspection (¶79)

210. Dr. Howe asserts that Rebotix's inspection methods are over-generalized and insufficient. But contrary to Dr. Howe's assertion that Rebotix provides technicians "no guidance on what the full intended range of motion should be,"160 Rebotix clearly specifies what a full range of motion for the mechanical wheels should be, as depicted in the image below, and in the accompanying rotational value table.161

[160] Howe Report, ¶79.

[161] REBOTIX133349.

Ref	EndoWrist	Yaw 1 in. oz f.		Yaw 2 in. oz f.		Pitch 3 in. oz f.		Rotation 4
		Clockwise	Counter Clockwise	Clockwise	Counter Clockwise	Clockwise	Counter Clockwise	Both Ways
420001	Potts Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420006	Large Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420007	Round Tip Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420036	Debakey Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420048	Long Tip Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420049	Cadiere Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420093	ProGrasp Forceps	2.0 - 4.6	2.4 - 5.6	2.0 - 4.0	2.6 - 5.0	2.0 - 6.5	4.3 – 9.7	.25 – 2.0
420110	Precise Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420171	Micro Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420172	Maryland Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420178	Curved Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420179	Monopolar Curved Scissors	3.0 – 5.6	4.0 – 11.0	3.0 – 7.0	3.0 – 7.0	3.0 – 6.8	4.2 – 10.7	.25 – 2.0
420181	Resano Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420183	Permanent Cautery Hook	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420184	Permanent Cautery Spatula	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	.25 – 2.0
420189	Double Fenestrated Graspers	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	.25 – 2.0
420190	Cobra Grasper	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420194	Mega Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420205	Fenestrated Bipolar Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420207	Tenaculum Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420227	PK Dissecting Forceps	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0
420296	Large SutureCut Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420309	Mega SutureCut Needle Driver	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	2.0 – 4.0	3.8 – 6.0	4.4 – 7.3	.25 – 2.0
420344	Curved Bipolar Dissector	2.9 – 7.8	2.0 – 5.0	2.0 – 4.0	3.2 – 6.0	3.2 – 7.5	3.2 – 7.5	.25 – 2.0

Table 1

REBOTIX129043

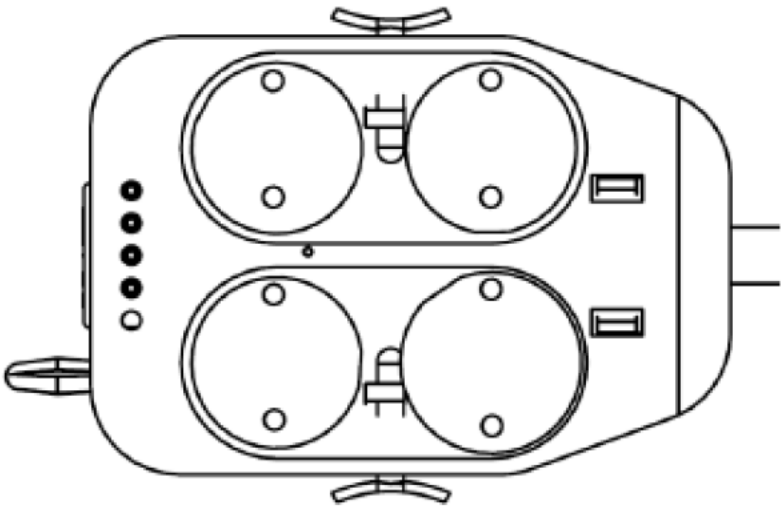


Figure 4

mechanical_degree_of_freedom_rotation

The device shall be capable of a rotational degree of freedom whereby the rotation wheel tab meets the full mechanical stop against the main body in both clockwise and counter-clockwise orientations.

REBOTIX17006

211. Further, the visual inspection of the EndoWrist inspects the components in the proximal housing, and verifies that the cables are functioning properly and free of fraying or breakage. It also verifies that the cables are properly engaging with the pulleys.[162]

212. Dr. Howe also asserts that "no inspection whatsoever is required for components within the proximal housing".[163] But numerous steps in the Rebotix service procedure and accompanying images show that this statement is false.

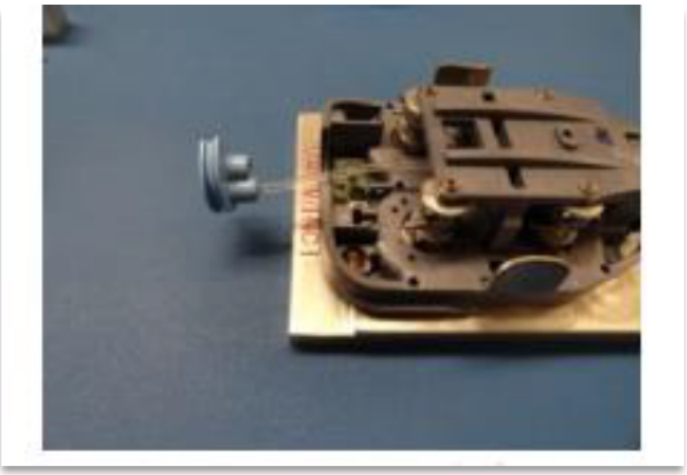
[162] *See, e.g.,* REBOTIX162442-162443.

[163] Howe Report, ¶79.

213. For example, Steps 6.4.1.2 and 6.4.1.3 require the operator to "evaluate cable movements in the housing and how the cable wraps around the cable spool."[164]

214. The accompanying images show the components in the proximal housing being subject to inspection:

REBOTIX162441

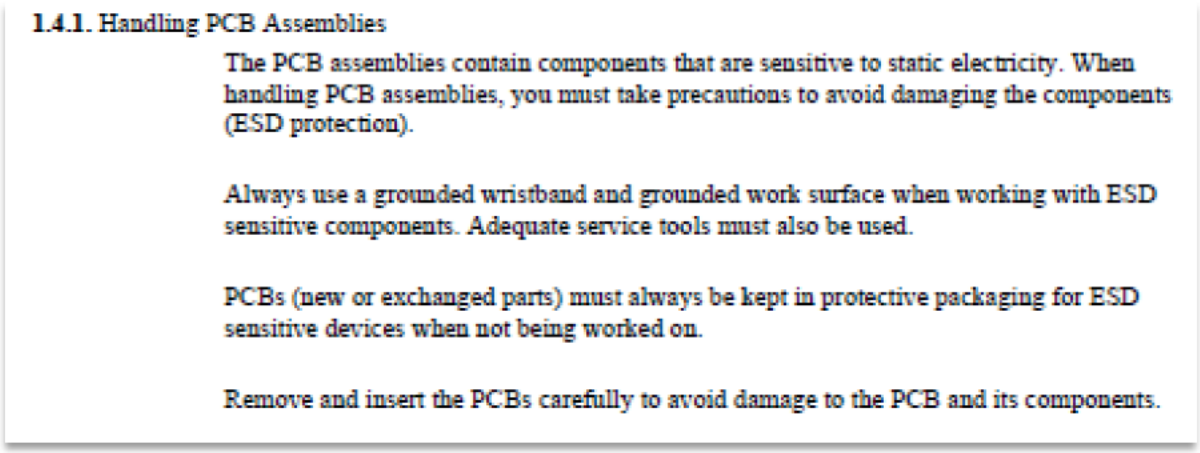


REBOTIX162439

[164] REBOTIX162442-REBOTIX162443.

d) Electrostatic discharge precautions and "shop air" (¶80)

215. Contrary to Dr. Howe's assertions, the Rebotix service procedure expressly includes instructions about electrostatic discharge.



1.4.1. Handling PCB Assemblies

The PCB assemblies contain components that are sensitive to static electricity. When handling PCB assemblies, you must take precautions to avoid damaging the components (ESD protection).

Always use a grounded wristband and grounded work surface when working with ESD sensitive components. Adequate service tools must also be used.

PCBs (new or exchanged parts) must always be kept in protective packaging for ESD sensitive devices when not being worked on.

Remove and insert the PCBs carefully to avoid damage to the PCB and its components.

REBOTIX162405

216. And, as discussed above, the ultrasonic cleaning process that the instrument is subjected to prior to being shipped back to the hospital addresses any potential contamination that would result from "shop air."[165]

e) Clarity of instructions (¶81)

217. As detailed previously, Dr. Howe ignores the underlying procedure documents that provide additional detail for each step in the Rebotix service process. Dr. Howe's only listed example, the use of TheraBand material in the sharpening of scissors, is addressed in the underlying procedure documents.

[165] *See, e.g.,* REBOTIX162422.

218. A TheraBand is a resistance band, and as discussed previously, the exact material is specified by Rebotix. The steps for testing the sharpness of scissors on TheraBand material is described in a specific procedure document.[166]

219. And as discussed previously, Rebotix's underlying procedure documents even further details about how the TheraBand material should be used in the repair process.[167]

B. Issues Dr. Howe identifies with risk management

a) Risk management related to wear and tear (¶¶82 – 89)

220. Dr. Howe asserts that Rebotix does not consider wear and tear suffered by instruments beyond the original number of uses.[168] This assertion is false.

221. First, Rebotix explicitly considers tear in its initial inspection of the instrument. any "tear" or breakage suffered by an instrument prior to Rebotix receiving that instrument renders it ineligible for repair. Instruments with broken scissors, snapped graspers, or frayed cables will not be repaired by Rebotix.

222. Second, as I discussed in detail, Rebotix's repair process accounts for any wear that the instrument has experienced. It accounts for the dulling of scissors or the misalignment of graspers. It accounts for any loss of tension in cables, as discussed in Section V. B,. above. And Rebotix's life testing confirms that the instrument continues to operate just as a new EndoWrist would through its additional lives.

[166] REBOTIX162422, at 6.4.2.3 "The scissors should cut at least the distal 2/3 of the cutting edges. If insufficient cutting is occurring the cutting edges may be dull…[a]lways remove burs created from sharpening by closing the jaws in a cutting motion on the TheraBand a few times".

[167] REBOTIX134642.

[168] Howe Report, ¶82.

b) Consideration of mechanical forces (¶¶83 – 89)

223. Dr. Howe claims that Rebotix's risk management protocols simply assume that Rebotix can restore the instrument to the same function as a new EndoWrist, and that it does not consider any risks from continued use significant.[169] But Rebotix's development of the repair process and its extensive testing of instruments beyond the original lives on the use counter refute this point.

224. Rebotix considered and took all potential failure modes of EndoWrists seriously in its design plan and testing. In its risk management documents, Rebotix concluded that any increase in "any estimated hazard severity or probability of occurrence" would need to be investigated and mitigated.[170] To that end, Rebotix conducted extensive life testing to ensure that its repaired EndoWrist instruments continued to operate and function in the same manner as new Intuitive EndoWrists. And Rebotix's life testing confirmed that its repairs resulted in no increase in hazard severity or probability of occurrence.

225. Dr. Howe further claims that Rebotix's failure to consider mechanical forces is demonstrated by its failure to mention those forces in its "Interceptor Circuit Card Risk Analysis and Assessment."[171] Just as the EndoWrist design does not place any mechanical load on the original circuit board, so too is there no load placed on the Interceptor assembly that replaces the circuit board. A conclusion that the Interceptor is not exposed to mechanical forces does not mean that Rebotix does not consider the role of those forces in its service process.

[169] Howe Report, ¶84.

[170] REBOTIX123794.

[171] Howe Report, ¶87. The "Interceptor Circuit Card Risk Analysis and Assessment" only deals with any additional risk from installation of the Interceptor, and concludes that mechanical forces do not act on that Interceptor assembly. See also REBOTIX084679.

c) MDR Report with Mechanical Failures (¶¶90 – 92)

226. Dr. Howe analyzes an MDR report and concludes that it shows that mechanical failures increased with the number of uses.[172] Dr. Howe asserts that the MDR report demonstrates that instruments wear over time.[173] And Dr. Howe claims that Rebotix ignored this data and that "ignored the damage that occurs in normal surgical use of these instruments."[174] I disagree.

227. Dr. Howe's conclusions based on this document are flawed.

228. First, the report only deals with a subset of reported returns. Intuitive receives, according to witness testimony, tens of thousands of RMA instruments per year.[175] The sampling of instruments in the report is not sufficiently broad to draw overall conclusions about instrument failures.

229. Second, Dr. Howe fails to discuss several other important conclusions contained in the report. About half of the returned EndoWrists in the report were misused, and were not simply subject to normal surgical use. Intuitive frequently attributes misuse or damage during reprocessing as the cause of specific failures.

> "After data examination, about half of the returned Endowrists could be considered misused. Misuse was defined as any action contrary to the directions for use (DFU) such as using an endowrist to clean another endowrist, overloading at the tip, tensile loading, excessive force on the grip, tip, or clevis, improper cleaning procedures, and improper set up the monopolar and bipolar cords."[176]

[172] Howe Report, ¶90.

[173] Id. at ¶92.

[174] Id. at ¶93.

[175] DeSantis depo tr., 202:7-22.

[176] REBOTIX090160.

230. The failure of misused instruments does not indicate that those instruments become more likely to fail over time. Misuse or external damage during cleaning and handling steps may occur at any time during the life of an EndoWrist.

231. Third, the report includes instruments that were subject to recalls for defective parts. For example, monopolar curve scissors had a recall that dealt with flaws in design that were causing failures.[177] As another example, the FDA issued a recall of large needle drivers.[178] These recalls make the report not representative of actual usage for instruments without defective parts.

232. Fourth, the report's discussion of instruments returned with remaining uses is not representative of typical failures for EndoWrists.

233. The MDR report page cited by Dr. Howe gives a sample of 61 instruments returned with lives remaining.[179] This is an incredibly small sample that does not take into account the remaining uses on the other instruments involved in the MDR report (well over 1000).

234. Fifth, the conclusions that Dr. Howe draws from the unrepresentative sample of instruments referenced in the MDR report are flawed.

235. Dr. Howe claims that this table with 61 instruments shows that instruments wear out and show increased failure rates with increased usage. But the number of instruments that were returned with 0 uses remaining (11) was the same as the number of instruments returned with 7, 8, and 9 uses remaining (11). And more instruments were returned with five uses remaining than were returned with one use remaining.

[177] REBOTIX090161-REBOTIX090162

[178] REBOTIX090166.

[179] REBOTIX090164.

236. Sixth, Dr. Howe ignores statements in the underlying MAUDE sub report about the inability to draw conclusions about usage data because it is so often not recorded.

> "In reviewing the bipolar class of instruments, there does not appear to have enough information in the database to show an increase of burns as the instrument is used. Lives remaining information was not captured in most of the records."[180]

237. The report provided the same conclusion for monopolar cautery instruments.[181]

238. Moreover, Dr. Howe's claim that Rebotix "ignores" damage that occurs to instruments is inaccurate. Dr. Howe does not account for the initial evaluation of instruments that Rebotix conducts. Rebotix's repair service begins with a thorough evaluation of the instrument that determines whether any issue exists that would make the instrument unsuitable for repair. Rebotix would not service any of the instruments that suffered cable breaks prior to their useful life expiring because of misuse.

C. Issues Dr. Howe identifies with life testing

a) Mechanical forces in Rebotix's testing (¶¶95 – 98)

239. Dr. Howe's assertion that Rebotix's testing does not take into account mechanical forces is false. Rebotix specifically includes numerous tests to expose instruments to excessive mechanical forces.

[180] REBOTIX089912.
[181] REBOTIX089913.

240. For example, in Rebotix's life testing, the following mechanical safety instruction is included in each of the testing procedures:

mechanical_safety_rough_handling

The Device shall withstand the stresses caused by rough handling as defined in IEC60601-1: 2005 15.3.1 Table 28 for Hand-Held device: Push 15.3.2, Drop 15.3.4.1, Molding stress relief 15.3.6. (Mold Stress Relief only)

REBOTIX132477

241. And Rebotix further ensures that the instruments are subjected to the same mechanical strains they would face during surgery. During life testing, Rebotix ensured that instruments are tested in a manner that corresponds with surgical use. The graspers were tested for their ability to successfully grasp tissue,[182] scissors were tested to successfully cut tissue,[183] and the electrosurgical instruments were tested to successfully cauterize tissue.[184] And each instrument's range of movement was tested in every direction—pitch, yaw, and rotation.[185]

242. To determine how many times each instrument should be tested in this way for each use, Rebotix surveyed a number of surgeons to establish the "high end number of manipulations/activations for any given function of the EndoWrist surgical tool end."[186] Rebotix established that this high-end number was 60 activations.

243. Rebotix then performed each separate part of its testing 72 times. Each instrument was manipulated in each direction 72 times per use. It grasped, cut, or cauterized tissue

[182] REBOTIX170283-REBOTIX170284.

[183] REBOTIX170075-REBOTIX170076.

[184] REBOTIX170077-REBOTIX170078.

[185] REBOTIX170075.

[186] REBOTIX170053.

72 times per use (using chicken breast as simulated tissue). Because Rebotix performed 11 life tests, each tool was required to pass 792 test interactions with the chicken breast.[187]

244. This testing reflects the mechanical wear that an instrument will experience during surgery, and tests even above the high end number of manipulations for an instrument to ensure that the instrument can be safely used.

245. Dr. Howe asserts that Rebotix's life testing with chicken breast is not adequate because there was no "significant force applied to the instruments."[188] Dr. Howe describes Rebotix's life testing as including "some interactions with chicken breast" but ignores the rigor of that testing. And Dr. Howe gives no reason as to why the forces experienced by an instrument in its interaction with chicken breast fail to approximate forces during surgery. To the contrary, Dr. Howe himself writes: "Animal tissue models (in this case a beef rib roast) or synthetic models are used to provide reaction forces that emulate the forces produced in surgical procedures.[189]

b) Rebotix's life testing results (¶99)

246. Dr. Howe asserts that "Intuitive life testing regularly produces failures."[190] And Dr. Howe concludes that the lack of failures during Rebotix's testing protocols demonstrates that Rebotix's life testing is inadequate and inferior to Intuitive's.[191] I disagree.

247. Dr. Howe does not consider the possibility that EndoWrists repaired by Rebotix exhibited no failures in life testing due to an effective and thorough repair process that results in a device that is in superior condition to a device that comes up the manufacturing

[187] *See e.g.* REBOTIX170075.

[188] Howe Report, ¶98.

[189] Id. at ¶56.

[190] Id. at ¶99.

[191] Id.

assembly line and is not subjected to the testing, adjusting, and repairing performed by Rebotix. Each of the devices that Rebotix repairs must meet an initial inspection to ensure that it is capable of being repaired. That device is then repaired and serviced, and tested again to ensure that it is fully functional. This service process is superior to Intuitive's manufacturing approach and results in devices in superior condition.

248. Dr. Howe's analysis is also flawed for three additional reasons.

249. First, Intuitive's life testing is on new EndoWrist instruments, and does not take into account the possibility of repair. Intuitive has never conducted any life testing on an instrument after that instrument has been repaired. For example, Intuitive has never determined the likelihood of cable failures after re-tensioning. These differences mean that life testing by Intuitive and life testing by Rebotix cannot be directly compared.

250. Second, much of Intuitive's life testing involves testing design changes or proposed alterations to a product, while Rebotix is merely validating the effectiveness and adequacy of a repair. Two of the example documents cited by Dr. Howe involved testing instruments with proposed changes "[t]o evaluate the proposed changes."[192] These design-stage tests are not comparable to Rebotix's testing of instruments that have already been used.

251. Third, Rebotix's life testing protocols adequately reflect the stresses that an instrument experiences during surgical use. The lack of failures during Rebotix's life testing protocols is indicative of the success of the repair, not the inadequacy of the life testing process.

c) Statistical analysis for number of uses (Howe ¶100)

252. Contrary to Dr. Howe's assertions, Rebotix performed its life testing using statistical analysis by using a specified number of samples to establish a particular level of

[192] Intuitive-00546360, Intuitive-00544497.

reliability. Rebotix initially identified the worst-case instruments that were most likely to fail testing. A worst-case model "means that no other [Endo]Wrists represent a greater risk of failure."[193] When selecting the EndoWrists that would undergo testing, Rebotix considered which of the parts at the end of the tool ends would suffer the highest stresses from surgery, and selected representative models that would test each different tool type.[194]

253. The Rebotix life testing protocols selected 22 samples of each of the identified worst case models of EndoWrists for testing "to provide the level of statistical significance at 90% confidence of 90% reliability when no failures are observed."[195] None of the samples that Rebotix tested for any of the instruments produced a failure, satisfying the desired level of statistical confidence.

d) Rebotix's safety margin (¶101)

254. Rebotix performed reprocessing cycles after each simulated surgical use cycle to model the stresses that the device would experience.[196] And, as discussed below, because Rebotix conducted two rounds of life testing, it exposed instruments to at least 20 additional reprocessing cycles. And none of the instruments experienced failure over the course of those reprocessing cycles.

e) Comparison of Intuitive's extended life testing and Rebotix's life testing (¶¶102 – 106)

255. Dr. Howe asserts that Intuitive's life testing for the Extended Lives Program illustrates that Rebotix's life testing is inadequate because "at least one instrument of every model

[193] REBOTIX146771.

[194] Id.

[195] REBOTIX170058.

[196] REBOTIX170053.

suffered failures by SUC [surgical use cycle] 22."[197] Dr. Howe further notes that 70 failures were observed from the sample of 250 units, and that "52 of those instruments failed as a result of cable drivetrain stretch/fatigue/yield."[198] Dr. Howe claims that these failures indicate that Rebotix's life testing is inadequate. I disagree with Dr. Howe's conclusion.

256. First, Intuitive's testing of new instruments does not translate to Rebotix's testing. Intuitive's testing as part of the Extended Lives Program tested instruments up to 22 surgical use cycles.[199] At no point during that process did Intuitive evaluate whether instruments could be repaired or serviced to continue operating.

257. By contrast, Rebotix's testing assumes the proper inspection and servicing of instruments every ten uses. One round of Rebotix's life testing involved instruments that had already been used for nine uses, that were then repaired by Rebotix and subjected to a further life testing for eleven uses. Rebotix also performed a second set of tests on instruments that had already been repaired by Rebotix and used for an additional ten uses beyond the initial life counter.[200] As part of that testing, Rebotix again performed the steps of its inspection and repair process before conducting testing. Rebotix's results verified that after repair, the instruments did not experience failures in an additional set of ten uses.[201] These results demonstrate that with proper inspection and repair after every ten uses, EndoWrist instruments can continue to be used safely. Intuitive's life testing does not take these regular inspections and repairs into account.

[197] Howe Report, ¶104.

[198] Id.

[199] Intuitive-00552535.

[200] REBOTIX132019.

[201] Id.

258. Second, Intuitive's life testing results suggest that Rebotix's repair process effectively addresses common issues that arise as instruments are used for extended periods of time. Failures due to cable and drive train stretch are addressed by inspection and tightening of cables during each Rebotix repair procedure. And in the event that a cable break occurs on an instrument prior to submission to Rebotix, that instrument will not be a candidate for service.

Executed on August 30, 2021, at Sunnyvale, CA.

Dr. T. Kim Parnell

Exhibit A

T. Kim Parnell, PhD, PE

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Sunnyvale, CA 94087

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Expertise Highlights

- Medical device/biotechnology – Cardiovascular, Orthopedic, Orthodontic
- Patents & Intellectual Property
- Product Liability; Personal Injury
- Consumer Electronics; Consumer Products
- Bluetooth, Zigbee, Wireless technology
- Plastics, Molding, & Manufacturing
- Composite Materials Design & Damage
- Materials & Metallurgy
- Failure Analysis & Reliability
- Fracture & Fatigue
- System Specifications & Test Procedures
- Telephone set design; keypads
- Finite Element Analysis of Structures and Fluid/Heat Transfer (FEA/CFD)
- User experience & system interaction
- User interface design
- Transducers, Accelerometers, MEMs
- Software design, development, QA
- Shock & Vibration Sensitivity
- Green energy: Wind energy, Solar, Electric Vehicles, Battery technology, Trackers
- Structural Mechanics, Fluid Mechanics, Heat Transfer, & Thermodynamics
- Piezoelectric components
- Vehicle & Heavy-Truck Crashworthiness
- ATV & Vehicle Design, Crashworthiness
- Group Manager & Project Leader; Strategic & Budgetary Planning responsibility

Education

Year	University	Degree Awarded
1984	Stanford University	Ph.D., Mechanical Engineering
1979	Stanford University	MSME, Mechanical Engineering
1978	Georgia Tech	BES, Engineering Science & Mechanics (Highest Honors)
2004	San Jose State University	Silicon Valley Executive Business Program (SVEBP)

Ph.D. Thesis: "Numerical Improvement of Asymptotic Solutions and Nonlinear Shell Analysis", June, 1984.

Professional Associations and Achievements

- Registered Mechanical Engineer (PE, M025550) in the State of California
- ASME Fellow; American Society of Mechanical Engineers (ASME)
- IEEE Senior Member; Institute of Electrical and Electronics Engineers (IEEE)
- Member, Society of Automotive Engineers (SAE)
- ASM International Member; SMST (Shape Memory and Superelastic Technologies) Member; EDFAS (Electronic Device Failure Analysis Society) Member
- IEEE-SCV Santa Clara Valley Section Leadership Award; 2018
- IEEE Santa Clara Valley (IEEE-SCV) Section; Chair-2011, Vice Chair-2010
- IEEE Consultants' Network of Silicon Valley (IEEE-CNSV), Board Member; Chair: 2008-2009
- NAFEMS Member – Composite Materials Working Group (CWG), Vice-Chair
- IEEE Vehicular Technology Society (IEEE-VTS); Vice-Chair, 2012-present.
- IEEE Consumer Electronics Society, IEEE Computer Society, IEEE Engineering in Medicine & Biology (IEEE-EMBS), IEEE Components, Packaging, and Manufacturing (IEEE-CPMT)
- Reviewer, *Journal of Composite Materials (JCM); International Journal of Forensic Engineering*
- Chinese American Semiconductor Professional Association (CASPA)
- The Bio2Device Group (B2DG); NanoBio*Convergence* (NBC), Board of Directors; Medical Device Network (MDN), Stanford University; CSIX Connect (CSIX), Board of Directors

Employment History

From: 2000 **Parnell Engineering & Consulting (PEC)**
To: Present Sunnyvale, CA; Web: parnell-eng.com
Position: *Principal & Founder*

Provides independent engineering consulting & expert witness services for high-technology applications including:

- Medical device/biotech product development & concept design
- Medical device cardiovascular applications across wide product range
- Medical device orthopedic, spinal, prosthetic devices – IP, design
- VC technical due-diligence for prospective medical device investment
- Patent & intellectual property – litigation, IPR, research, due diligence
- Expert Witness & Litigation Support services – multiple technologies
- Nitinol, shape-memory applications; biomaterials applications
- Portable devices, keypads: robust design, reliability & durability
- Cell phone Li-Ion battery failure & fire;
- Bluetooth, Cellular, Zigbee, Wireless technology
- Solar panel tracker technology
- Manufacturing technology; materials applications (metals, polymers)
- Reliability and failure analysis services; accelerated testing
- Research in application & damage of composite materials
- Teaching intensive workshops & training seminars on simulation, design, and reliability for practicing engineers
- Lecturer in Prof. Steve Tsai's *Stanford Composites Design Workshop*
- Composite materials design & applications
- Wind Energy, Solar Energy, Alternative Energy – technology
- Electric vehicles, battery systems: design & development
- Heavy-Truck Rollover, Vehicle & ATV Crashworthiness; Barriers
- Software design, development, user experience, QA, testing
- Application of CAE, FEA, and High-Performance Computing (HPC)

From: 2010 **Santa Clara University**
To: 2012 Santa Clara, CA
Position: *Faculty, Mechanical Engineering Department*

Taught courses covering a range of topics including Materials Science, Manufacturing Methods, Composite Materials, Finite Element Methods, Mechanism Dynamics, Computer Graphics, & Design. Advised students on Design, Safety, and Simulation for Student Projects including SAE Formula-Hybrid Vehicles. Research in Composite Materials and High-Performance Computing. Interaction with Industry Advisory Board (IAB) & ABET Certification. Teamed with other faculty for strategic initiatives and equipment/tool grants for research. Promote IEEE, ASME, cross-disciplinary initiatives & social media avenues for student networking, professional development & project support.

From: 2006 **MSC Software Corporation**
To: 2010 Sunnyvale, CA
Position: *Senior Manager, User Experience; Lead Application Engineer*

Integrated feedback from customers into user interface design & specifications; Beta testing of prototypes with users; CAE software Product Management role for user interface and analysis tools including:

- Product quality, testing, and improvement; drove customer satisfaction
- Application of advanced analysis technology in design & manufacturing
- Led corporate Wind Energy initiative & revival of Fatigue product
- Composite materials – acknowledged corporate & customer expert
- Customer training courses, workshops, webinars; developed & taught
- Software design, development, QA, testing of commercial apps
- Mentoring and development of junior staff; interviewed & hired staff for India; developed and trained staff using distance learning

Applied finite element technology to applications including automotive, medical device, and electronics. Created customer satisfaction via:

- Customer support & analysis process development
- Material testing & data reduction for development of properties

From: 1999 **Rubicor Medical, Inc.**
To: 2000 Redwood City, CA
Position: *Director of R&D*

Led the R&D team for this start-up medical device company developing breast diagnostic and therapeutic devices. Designed device considering interaction of Physician with Device and human factors. System included a mechanical subsystem and RF generator/control electronics. Developed initial prototypes and conceptual designs; researched IP and competing technologies.

From: 1986 **Exponent, Inc. and Failure Analysis Associates (FaAA)**
To: 1999 Menlo Park, CA
Position: *Senior Managing Engineer*

Delivered consulting services for failure analysis, accident investigation, product liability, patent/IP, insurance-related litigation, medical device and biotechnology product development, FDA submission, and forensic/failure investigation. Performed analyses involving stress, thermal, & fluid applications; testing of material properties and use of laboratory techniques such as SEM & Optical Microscopy for inspection of material samples. Led the SAE Heavy Truck Crashworthiness, Phase II project with testing & simulation of heavy-truck cabs in rollovers. Managed the Engineering Analysis Group and had profit/loss responsibility for the Engineering Computer Center. Maintained high personal utilization/billable hours and had increasing personal/group profitability with consulting services revenue generation >$600K.

From: 1995 **Stanford University**
To: 1996 Stanford, CA
Position: *Visiting Associate Professor, Mechanical Engineering Department*

Taught graduate courses in Theory of Plates and Theory of Shells in the Applied Mechanics Division (now Mechanics & Computation) of Mechanical Engineering. Part-time appointment while full-time staff-member at Exponent.

From: 1984 **SST Systems, Inc.**
To: 1986 Sunnyvale, CA
Position: *Principal Engineer in Pressure Vessels, Piping & Structures Division*
Managed software development, facilitated university collaboration, developed product specifications and enhancements based on customer feedback, supported and trained over 30 new customers, and created standardized product documentation. Provided sales and technical marketing support to CEO during product launch; formulated go-to-market campaign.

From: 1980 **Stanford University**
To: 1984 Stanford, CA
Position: *Research Assistant, Mechanical Engineering Department*
Established the theoretical basis and developed computational tools for nonlinear shell mechanics. Emphasized computational mechanics and engineering applications, including linear & nonlinear finite element methods and other numerical analysis techniques.

From: 1978 **AT&T Bell Laboratories**
To: 1980 Indianapolis, IN
Position: *Member of Technical Staff (MTS), Physical Design Group*
Design, development, and manufacturing of high-volume telecommunication components. Researched and designed dials, keypads, electromechanical systems, and piezoelectric polymer applications. Employed range of materials including elastomers, metals, polymers, and piezoelectrics for keypad and transducer applications. Emphasis on cost, reliability, and manufacturing simplicity. Developed new technologies to ultimately drive field improvements. Applied finite element simulation to improve designs and reduce prototypes.

From: 1976 **General Motors Corporation**
To: 1977 Atlanta, GA
Position: *Engineering Assistant, Plant Engineering Department*
Production line design and manufacturing applications for the GM Lakewood assembly plant. Supervised demolition and production line installation during changeover. Installed automated spotweld robot for sheet metal panels. Studied automotive manufacturing & assembly operations from start to finish.

Selected Grants & Research Programs

SA Photonics, Inc.

- 2013 – Phase I Navy SBIR – Post-IED Hull Inspection Tool, Topic N123-156

Stanford University

- 2012 – Phase II Army SBIR – Development and Implementation of Micro-Mechanics of Failure (MMF) Model for Composites in Commercial Finite Element Codes

Santa Clara University

- 2012 – Kuehler Summer Undergraduate Research Grant – student support for composite materials testing & characterization
- 2011 – Technology Innovation Grant – Acquisition of advanced DSC/TGA System for improved lab capability

- 2011 – Technology Innovation Grant – Acquisition of High-Performance Workstation for advanced simulation of large dynamic and nonlinear systems
- 2011 – Technology Innovation Grant – Materials Laboratory equipment upgrades and reorganization

Selected Presentations

"SMA Seismic Damping Devices: Fabrication, Testing, Analysis, and Projections", SMST-2014, Monterey, CA, May, 2014.

"Mechanical Design for Reliability: What does it Mean?", ASME Santa Clara Valley Section, Sunnyvale, CA, Mar, 2014.

"Prosthetic Feet using Carbon Fiber Composites: Design, Simulation, & Testing", ASME Santa Clara Valley Section, Jun, 2013.

"Mechanical Design for Reliability: Beating the Tough Problems", IEEE-SCV Reliability Society, Santa Clara, CA, Jun, 2013.

"Prosthetic Feet using Carbon Fiber Composites: Design, Simulation, & Testing", MSC Software 50th User Conference, Irvine, CA, May, 2013.

"Composite Materials: Improved Understanding of Composite Failure Mechanisms with DIC Testing & Analysis", Trilion User Conference, Philadelphia, PA, Sep, 2012.

"Medical Device Failures – 'Not so Good, Very Bad, and Truly Ugly'!!", ASM (Materials Information Society) Santa Clara Valley Chapter, May, 2012.

"C-Ply Bi-Angle NCF Tape Seam Assessment & Design Considerations for Automated Tape Laying", Composites Design Forum, JEC Composites Conference, Paris, Mar, 2012.

"Failure of Structures Designed with Composite Material – Delamination", *'Meet the Experts' Forum on Composite Materials*, Joint with Prof. Steve Tsai, SMP Tech, Feb 28, 2012.

"Shape Memory Alloy Fundamentals & Advanced Simulation Techniques for Medical Products", *'Meet the Experts' Forum on Nitinol Properties and Unique Behavior for Medical Product Design*, SMP Tech, Sep 14, 2011.

"Stiffness and Strength of Laminates Fabricated with Bi-Directional Tape", ICCM-18 (International Conference on Composite Materials, Korea, Aug, 2011, (with Daniel D. Melo & Christine Tower))

"Composite Materials – Damage & Delamination", Santa Clara University, Mechanical Engineering Seminar, Feb, 2011

"Composites Damage, Delamination, Failure & Curing" and "Workshop on Mic-Mac/FEA" with Prof. Steve Tsai, Stanford Composites Design Workshop, 2010-2012

"Composite Damage, Delamination, and Failure" and "Workshop on Mic-Mac/FEA" with Steve Tsai, Stanford Composites Design Workshop, Jan, 2010

"Composite Failure Methods – Application Comparisons", Composites Durability Workshop-14 (CDW-14), UCLA, Jul, 2009

"Composites Damage, Delamination, and Failure Analysis", Stanford Composites Workshop, May 2009

"Finite Element Analysis using a Thermomechanical Shape Memory Alloy Model", SMST-2006, Monterey, CA, 2006.

"Medical Device Issues & Trends", in "Biomedical Wave: Opportunities for Non-Biologists**",** MedTech Bridge Seminar Series, 2005.

"Medical Device Development and Entrepreneurship", IEEE Consultants' Network of Silicon Valley (IEEE-CNSV), www.CaliforniaConsultants.org , 2004.

"CFD Fundamentals and Applications in Biotechnology", ASME Professional Development Seminar, 2003 & 2004.

"Medical Device Business Opportunities in China", multiple presentations to key government and industry representatives, CASPA Delegation, Oct, 2003.

"Using Simulation with Testing for Maximum Benefit", WESCON 2003, Low Cost Tools: Alternatives for Problem Solving in Development, Design and Application, San Francisco, CA, Aug, 2003.

"Fracture Mechanics: Overview and Applications", Aeronautics & Astronautics Department, Stanford University, May, 1999.

"Integrated Fluid/Thermal/Structural Analysis of a Turbine Blade", American Society of Mechanical Engineers Bay Area Technical Conference, May, 1995.

"Failure Analysis Projects", Mechanical Engineering Department, Stanford University, May. 1992.

"Finite Element Applications in Failure Analysis", Mechanical Engineering Department, Stanford University, Mar, 1991.

"Soil-Pipeline Interaction Associated with a Process-Plant Explosion", Seminar in Solid Mechanics, Stanford University, Nov, 1989.

"*Typical* Failures: Causes and Consequences", Construction Engineering and Management Program, Civil Engineering Department, Stanford University, 1989.

"Shell Analysis Using Personal Computers", Solid Mechanics Seminar, Stanford University, 1985.

Selected Publications

"Numerical Simulation of Seismic Response Control of Frame Structure Using High-Temperature Shape Memory Alloy Wire"; In proceedings of: International Conference on Earthquake Engineering (SE-50EEE), At MAEE, Skopje, Macedonia, May 2013, (with Md. Golam Rashed and Raquib Ahsan).

"Equivalent Properties for Finite Element Analysis in Composite Design", JEC Composites Magazine, No.68 (Bi-Angle NCF Special Issue), Oct, 2011, (with Stephen W. Tsai)

"Stiffness and Strength of Laminates Fabricated with Bi-Directional Tape", ICCM-18, Aug, 2011, (with Daniel D. Melo & Christine Tower)

"How Reliable Is Your Product: 50 Ways to Improve Product Reliability", Mike Silverman, 2011 (2-Book Chapters contributed by T.Kim Parnell).

"Heavy Truck Roll Cage Effectiveness", IMECE2009-12423, Proceedings of IMECE: ASME-Mechanical Engineering Congress and Exposition, Nov, 2009, (with Stephen Batzer, Bruce Enz, Grant Herndon, Chandrashekar Thorbole, Robert Hooker, and Mariusz Ziejewski).

"Composite Failure Methods – Application Comparisons", Proceedings of Composites Durability Workshop-14 (CDW-14), UCLA, Jul, 2009

"Thermoelastic Shape Memory Modeling of Medical Devices with FEA", SMST-2006, The International Conference on Shape Memory and Superelastic Technologies, ASM International, May, 2006, (with Sanjay Choudhry and Jesse Lim).

"Finite Element and Fatigue Analysis of CardioVasc Stent Graft", CardioVasc, Inc., 2004.

"Analysis of Rail Cracking and Development of a Rail Screening Guideline Based on Fracture Mechanics Principles", Fatigue & Durability Assessment of Materials, Components & Structures, Proceedings of the Fifth International Conference of the Engineering Integrity Society, Queen's College, Cambridge, UK, Apr 7-9, 2003.

"Finite Element and Fatigue Analysis of CP Stent Expansion", NuMed, Inc., 2003.

"Evaluation of a Failure in a Chlorine Production Facility", Proceedings of IMECE 2001, ASME International Mechanical Engineering Congress and Exposition, Nov, 2001, New York, NY (with S. Andrew, R. Caligiuri, and L. Eiselstein).

"Physical Testing for Good Analysis: Experimental Validation for Quality Finite Element Analysis of Medical Devices", feature article for *ANSYS Solutions*, Fall 2000 (Machine Design Custom Media, Penton Media, Inc.).

"Finite Element Simulation of 180° Rollover for Heavy Truck Vehicles", ASCE Engineering Mechanics Conference, Baltimore, MD, Jun, 1999 (with Christopher V. White and Shari E. Day).

"Finite Element Analysis of the S670 Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1999.

"Finite Element Analysis of the S660 Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1999.

"Finite Element Analysis of the Six Crown Extra Support Renal Stent – Minimum Dimensions", Arterial Vascular Engineering, Inc., 1998.

"Finite Element Analysis of the SVG Stent", Arterial Vascular Engineering, Inc., 1998.

"Finite Element Analysis of the GFX-II Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1998.

"Analysis of Drill Pipe Joint Failures and Recommendations For Service", Failure Analysis Associates, Inc. Report, Nov, 1997 (with R.D. Caligiuri, L.E. Eiselstein, M. Wu, R. Huet).

"Finite Element Analysis of the GFX Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1997.

"Stress Analysis: AVE MicroStent-II Cardiovascular Stent", Arterial Vascular Engineering, Inc., 1997.

"SAE Report CRP-12 Heavy Truck Crashworthiness – Phase II (180° Dynamic Rollover, Static Roof Crush Simulation)", SAE Headquarters, 1997.

"Heavy Truck 180º Dynamic Rollover and Static Roof Crush Simulation", Failure Analysis Associates, Inc. Report, Apr, 1996 (with C. White, S. Day, T. Khatua, and L. Cheng).

"Fracture Toughness by Small Punch Testing", *Journal of Testing and Evaluation*, Vol. 23(1), pp. 3-10, Jan, 1995 (with J. R. Foulds, P. J. Woytowitz and C. W. Jewett).

"Safety Analysis of Custom Designed Manufacturing Equipment", Proceedings, American Society of Mechanical Engineers Winter Annual Meeting, Safety Engineering and Risk Analysis, New Orleans, Louisiana, Nov, 1993, Vol. 1, pp. 111 (with G. L. Rao and R. D. Caligiuri).

"American Azide Corporation Reactor and Dryer Safety Studies", Failure Analysis Associates, Inc. Report, Jan, 1993 (with G. L. Rao, V. B. Rao, and R. D. Caligiuri).

"Combustion Tests on and Chemical Analysis of Therminol 66 Heat Transfer Fluid Used at American Azide", Failure Analysis Associates, Inc. Report, 1993 (with A. Reza and R. D. Caligiuri).

"Gas Release from Leaky Natural Gas Pipeline: The PEPCON Explosion in Henderson, Nevada", Failure Analysis Associates, Inc. Report, 1992 (with A. Reza, M. El-Fadel and R. D. Caligiuri).

"Computational Modeling of Dynamic Failure in Armor/Anti-Armor Materials", Failure Analysis Associates, Inc. Final Report to U.S. Army Research Office, Contract DAA-L03-88-C-0029, May, 1992.

"Analysis of Cracking in the Windsor Recovery Boiler Superheater", Failure Analysis Associates, Inc. Report to Domtar, Inc., Apr, 1992 (with R. D. Caligiuri, C. H. Lange and S. P. Andrew).

"Analysis of the Dynamic Response of a Buried Pipeline due to a Surface Explosion", *Computational Aspects of Impact and Penetration*, L.E. Schwer and R.F. Kulak, eds., Elme Press International, 1991 (with R. D. Caligiuri).

"Failure Analysis of Aerzen Screw Compressor Male Thrust Bearings", Failure Analysis Associates, Inc. Report to AECI Chlor-Alkali & Plastics, Ltd., Sep, 1991 (with C. C. Schoof).

"Gas Flow and Heat Transfer in a Pipe Tee Joint", Failure Analysis Associates, Inc. Report to Chevron Corporation, Nov, 1990 (with R. D. Caligiuri and A. Reza).

"Development of Dynamic Failure Criteria for Ceramic Armor Materials", Failure Criteria and Analysis in Dynamic Response Symposium, ASME Winter Annual Meeting, Nov, 1990, H.E. Lindberg, ed.

"DYNA3D Analysis of the Dynamic Response of a Buried Pipeline due to a Surface Explosion", DYNA3D User Group Conference, Bournemouth, Dorset, United Kingdom, Sep, 1990.

"Con Edison Hellgate Facilities Gas Main Rupture", Failure Analysis Associates, Inc. Report to Consolidated Edison Company of New York, Inc., Feb, 1990.

"Stress and Fracture Mechanics Analysis of Weld Cracking in a Rotary Ball Mill", American Society of Mechanical Engineers Winter Annual Meeting, Paper 89-WA/DE-17, San Francisco, California, Dec, 1989 (with C. A. Rau, Jr., H. F. Wachob and E. L. Kennedy).

"Analysis of the Plunger-to-Plunger Rod Joint in an Automotive Fuel Injector", Failure Analysis Associates, Inc. Report to Hitachi, Ltd., Oct, 1988 (with P. R. Johnston and B. Ross).

"Analysis of the Circumferential Seam Weld Cracking of Raw Grinding Mills", Failure Analysis Associates Report to Kaiser Cement Corporation, Nov, 1986 (with C.A. Rau, Jr., H.F. Wachob).

"Local Flexibility and Stresses in Cylindrical and Spherical Shells Due to External Loadings on Nozzles and Lug Attachments", A.F.I.A.P. Conference, Paris, France, Oct, 1986.

"Analysis of Piping Systems with Local Nozzle Flexibility Using Personal Computers", American Society of Mechanical Engineers Pressure Vessel and Piping Conference, New Orleans, LA, 1985.

"Numerical Improvement of Asymptotic Solutions and Nonlinear Shell Analysis", Ph.D. dissertation, Stanford University, Jun, 1984.

"Numerical Improvement of Asymptotic Solutions for Shells of Revolution with Application to Toroidal Shell Segments", *Computers & Structures*, Vol. 16, No. 1-4, 1982.

Consulting Projects - Selected

Client: Silver Spring Networks, Inc.; Ops A La Carte LLC
Project: Mechanical Accelerated Life Testing and Reliability Assessment of Commercial IoT Network-Connected Natural Gas Metering Equipment; Failure Analysis support; plastic component design, accelerated life testing; remote monitoring;

Client: F-Prime Capital Partners (former Fidelity Biosciences)
Project: Technical Due-Diligence review of prospective stealth-mode medical device investment

Client: SI-Bone, Inc.
Project: Design review of iFuse sacroiliac (SI) joint fixation devices; Competitive comparison

Client: TexasLDPC, Inc.
Project: Business Advisor; Flash Memory Technology development for error-correction; LDPC – Low-Density Parity Check; start-up

Client: Cerevatech Medical, Inc.
Project: Business Advisor; Medical Device developer of innovative Nitinol neurovascular stent and flow diverter devices, start-up

Client: Promed Medical Inc.
Project: Evaluation of deployment failure associated with Nitinol scaffold and bioabsorable PLGA cover material. Test protocols; assessment of data and development of strategy to increase device reliability.

Client: Topera Inc.
Project: Evaluation of Nitinol device failure in test and clinical setting used for 3D mapping associated with treatment of arrhythmia. Comparison of current design with proposed redesign.

Client: LC Therapeutics
Project: Assessment of Nitinol coronary device.

Client: CrossRoads Extremity Systems
Project: Design evaluation of Nitinol orthopedic devices for bone fixation with focus on foot & ankle devices including staples and plates; Report for 510K submission to FDA

Client: Bridgelux, Inc
Project: Design evaluation of LED Outdoor Lighting Module (OLM) for assembly and service conditions; assessment of polymeric, injection-molded components including FRP (fiber-reinforced plastic)

Client: Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
Project: MEMs Patent Portfolio review and assessment

Client: Design Standards Corporation (DSC)
Project: Design analysis & report for injection-molded surgical ligation clip;

Client: Sirius Engineering LLC
Project: Nitinol Vena-Cava Filter; Implantable cardiovascular medical device

Client: Nitinol Technology, Inc.
Project: Design and assessment of large-scale nitinol components for seismic damping in civil structures (buildings, bridges, roadways); analysis & testing collaboration

Client: Varian Medical, Inc.
Project: Medical radiation oncology capital equipment; shipping hazard assessment

Client: Atsina Surgical LLC
Project: Injection molded surgical ligation clip; material testing; product design, development, and optimization

Client: Home Dialysis Plus
Project: Development of reliability & accelerated testing protocols for innovative dialysis system including mechanical, electronic, & software components

Client: Freedom Innovations, LLC
Project: Carbon Fiber Prosthetic Foot – failure analysis, simulation

Client: Ops A La Carte LLC
Project: Mechanical Design for Reliability classes; failure analysis; simulation of mechanical & thermal performance; accelerated testing and root-cause analysis; solar tracker design, failure analysis, full system loss due to wind;

Client: OLT Solar
Project: Product improvement under high-temperature exposure

Client: VX Aerospace
Project: Composite material product design and validation

Client: Fidelity Biosciences
Project: Medical device due-diligence and technology evaluation pre-investment

Client: DJS Associates
Project: Automated food packaging equipment - failure analysis and assessment of root cause issues

Client: Tribal Engineering, LLC
Project: Various simulation and customer training projects

Client: Gerson Lehrman Group
Project: MEMs Sensors; Various other projects

Client: Ops A La Carte LLC
Project: Various Reliability Consulting projects; Mechanical Design for Reliability Training

Client: Revascular Therapeutics, Inc (acquired by Boston Scientific)
Project: Implantable medical device for treatment of calcified lesions

Client: City and County of San Francisco
Project: Glass failure; Trial prep

Client: Sagalio LLC
Project: Retractable screen for portable cellular devices

Client: New Energy Technologies, Inc
Project: Alternative Energy concept assessment & review

Client: Square One Medical
Project: Implantable medical device design, development, simulation

Client: Kyphon
Project: Device improvement for spinal interventional device

Client: ProMed, Inc
Project: Implantable medical device for spinal application

Client: Nuvation
Project: Instrumentation assessment

Client: Ovalis, Inc
Project: Nitinol PFO Closure Device development and design improvements

Client: Gateway Medical
Project: Vascular Closure Device

Client: Ensure Medical
Project: Vascular Closure Device

Client: Abbott Laboratories
Project: Continued development and cost reduction aspects for StarClose device.

Client: Integrated Vascular Solutions (IVS) (acquired by Abbot Labs)
Project: Design & development of StarClose nitinol closure device for arterial closure following interventional procedures. 2005 MDM Excellence Award

Client: Prolifix Medical
Project: Nitinol device to excise plaque buildup from arteries

Client: Coapt Systems
Project: Bioabsorbable devices for surgical and cosmetic procedures

Litigation Support Experience

Litigation Cases; Depositions & Expert Reports as Shown:

2019	Client:	Venable LLP
	Case:	*Disc Disease Solutions, Inc., vs. VGH Solutions, Inc. Dr-Ho's Inc., Hoi Ming Michael Ho.* Case No. 1:15-cv-00188-LJA, United States District Court, Middle District of Georgia, Albany Division
	Project:	Patents; Medical Device, Back-Pain Relief;
	Status:	Claim construction, invalidity, non-infringement; Claim construction Declaration Aug 2019; Settled
2019	Client:	Baker & Hostetler, LLP
	Case:	*Zadro Products, Inc. vs. SDI Technologies, Inc. d/b/a iHOME.* Case No. 17-1406 (WCB) in the United States District Court for the District of Delaware
	Project:	Patents; Consumer products, LED lighting, mirrors
	Status:	Settled
2019	Client:	Gardella Grace P.A.
	Case:	*Fulfillium, Inc. vs. ReShape Medical, LLC, SV Health Investors, LLC, Intersect Partners, LLC and ReShape Lifesciences, Inc.* Case No. 8:18-cv-01265-RGK-PLA United States District Court, Central District of California, Western Division
	Project:	Patents; medical devices, balloons, weight control
	Status:	Deposition Aug 2019; Expert Report Aug 2019; Declaration on Motion for Summary Judgement Aug 2019; Settled
2019	Client:	Merchant & Gould
	Case:	*Carlson Pet Products, Inc. v. North States Industries, Inc..* Case No. 17-cv-02529- PJS-KMM, United States District Court for the District of Minnesota
	Project:	Patents, Consumer product; Pet barrier
	Status:	Declaration, Oct 2019; Settled
2019 to Present	Client:	Todd Tracy Law Firm
	Case:	Multiple cases
	Project:	Heavy-truck rollover & crashworthiness; design assessment; product liability
	Status:	Ongoing
2019	Client:	Sterne, Kessler, Goldstein & Fox, P.L.L.C. (SKGF)
	Case:	*Lutron v. Geigtech*
	Project:	Patent Post-Grant Review (PGR); Other PTAB actions
	Status:	Suspended

2019 to Present	Client:	Faegre Baker Daniels LLP
	Case:	Confidential
	Project:	Confidential
	Status:	Ongoing
2019 to Present	Client:	Rouda Feder Tietjen McGuinn
	Case:	*Margo Schein v. Peak Pilates*
	Project:	Inspection of Pilates Reformer equipment; Accidental injury root-cause assessment
	Status:	Ongoing
2019	Client:	Manning & Kass, Ellrod, Ramirez, Trester LLP
	Case:	*Randy and Giselle Hoehn v. Summit to Sea LLC, Pet Pressure LLC.*
	Project:	Hyperbaric pressure chamber inspection, operation, and design review. Accidental injury investigation.
	Status:	Settled
2018 to Present	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Miriam Naramore v. Daimler Trucks North America, LLC.* Civil Action No. 1:18-CV-00156 in United States District Court for the Middle District of Georgia, Albany Division.
	Project:	Heavy-truck rollover & crashworthiness; design assessment
	Status:	Ongoing
2018 to 2019	Client:	Klein, DeNatale, Goldner, LLP
	Case:	*H&M Gopher Control, Allen Hurlburt v. Benchmark Pest Control, Inc., Andrew Ozanich.* Case No. 1:17-CV-01700-JLT, United States District Court for the Eastern District of California
	Project:	Patent technology for control of rodents
	Status:	Expert Report, Jan 2019; Settled
2018 to 2019	Client:	Cypress LLP
	Case:	*Kore Essential, Inc v. Nexbelt, LLC.* Case No. 3:17-CV-02129-CAB-JMA, United States District Court for the Southern District of California
	Project:	Patent technology for Ratchet Belt system
	Status:	Expert Report, Feb 2019; Settled
2018 to 2019	Client:	Pillsbury Winthrop Shaw Pittman, LLP
	Case:	*Lite-On Technology Corp v Darfon Electronics Corp,* Case No. 3:18-cv-02776, United States District Court, Northern District of California.
	Project:	Keyboard technology patents
	Status:	IPR Declaration Dec 2018; Settled

2018 to 2020	Client:	Honigman Miller Schwartz & Cohn LLP
	Case:	*Tim A. Fischell, Robert E. Fischell, and David R. Fischell v. Cordis Corp, Abbott Laboratories and Abbott Cardiovascular Systems, Inc.*, United States District Court for the District of New Jersey; Civil Action No. 3:16-cv-00928-PGS-LHG
	Project:	Patent family associated with cardiovascular stents
	Status:	Declaration, Apr 2019; Settled
2018	Client:	Akerman, LLP
	Case:	*Qbex Computadores S.A v. Intel Corporation,* United States District Court, Northern District of California, San Jose Division.
	Project:	Cellular phone ARM microprocessor, alleged product design defect associated with CPU overheating
	Status:	Settled
2018 to 2019	Client:	Davidson, Davidson & Kappel LLC
	Case:	ArcelorMittal Project
	Project:	Patent IPR associated with solar panel trackers
	Status:	Deposition Dec 2018; IPR Declaration Mar 2018; Settled
2018 to 2019	Client:	Ropes & Gray LLP
	Case:	*CPI Card Group, Inc. v. Multi-Packaging Solutions, Inc* , United States District Court for the District of Colorado
	Project:	Patent associated with secure packaging of transaction/gift cards; Testing
	Status:	Ongoing
2017 to 2018	Client:	Rimon Law
	Case:	*Imogene D. Johns v. Invacare Corporation,* Tulare County Superior Court Case No. 270201
	Project:	Alleged medical equipment product defect
	Status:	Settled
2017 to 2018	Client:	The Scranton Law Firm
	Case:	*Cesar Lopez & Moses Sepulveda v. DOES-1*
	Project:	Alleged design defect in ATV Rollover Protection System (RoPS); Design and Failure Analysis
	Status:	

2017 to Present	Client:	Troutman Sanders LLP; Vinson & Elkins
	Case:	*Blackbird Tech LLC d/b/a Blackbird Technologie v. Lenovo (United States) Inc.;,* C.A. No. 16-cv-140-RGA, United States District Court for the District of Delaware
	Project:	Patent infringement allegations around laptop computer screen display technology
	Status:	Declaration May 2018; Deposition Feb 2018; Reply Report Dec 2017; Non-Infringement Report Nov 2017; Invalidity Report Sep 2017; Settled
2017	Client:	White & Case LLP
	Case:	*Maquet Cardiovascular LLC v. Abiomed Europe GmbH and Abiomed R&D, Inc.*; C.A. No. 1:16-CV-10914, United States District Court for the District of Massachusetts
	Project:	Multiple Patent & Technology dispute associated with Implantable Circulatory Support System Pumps
	Status:	
2017 to Present	Client:	Baker & Hostetler, LLP
	Case:	*SCA Hygiene Products AB et.al., SCA Tissue North America, LLC v. Tarzana Enterprises, LLC;* United States District Court, Western District of Wisconsin, No. 3:16-cv-00728
	Project:	Patent infringement claims associated with paper goods manufacturing, stacking, folding, and packaging methods and equipment
	Status:	Depositions (2) Sep 2018; IPR Response Declarations, Jul 2018 (2), May 2018; Settled
2017	Client:	Vinson & Elkins
	Case:	*Inter Partes* Review of U.S. Patent No. 7,129,931; *Lenovo (United States) Inc. v. Blackbird Tech LLC d/b/a Blackbird Technologies, IPR2017-yyyy*
	Project:	Patent IPR involving laptop computer display apparatus
	Status:	Deposition Feb 2018; Expert Report; IPR Declaration May 2017;
2017 to Present	Client:	The Joe C. Savage Law Firm
	Case:	*Bauer v. Parks, Hyundai Motors America, and Deskins Motor Company and other related cases;*
	Project:	Vehicle Accident Investigation, Design, Crashworthiness, Fire
	Status:	Ongoing

2017 to 2018	Client:	Hill, Kertscher & Wharton, LLP
	Case:	*Trans Technologies Company v. Hendrickson USA LLC, et.al.*, United States District Court for the Northern District of Georgia, Atlanta Division, Civil Action No. 1:16-cv-01778-AT
	Project:	Patent litigation involving heavy-truck tire inflation/deflation technology
	Status:	Deposition Jul 2018; Deposition Apr 2018; IPR Declaration Aug 2017; IPR Reply Declaration Feb 2018; Settled;
2017 to 2018	Client:	Morgan, Lewis & Bockius LLP
	Case:	*Advanced Circulatory Systems, Inc. v. AutoMedx, Inc.,* and *AutoMedx, Inc v. ZOLL Medical Corp., Advanced Circulatory Systems, Inc.;* CPR Institute for Dispute Resolution, CPR File No. G-16-07
	Project:	Medical Ventilator Technology Development; Medical equipment
	Status:	Settled
2017	Client:	Dorsey & Whitney LLP
	Case:	*Hovik Nazaryan v. FemtoMetrix Inc.*, Superior Court of the State of California for the County of Orange Case No. 34-30- -2015-00795246-CU-BC-CJC
	Project:	Semiconductor lithography equipment technology development
	Status:	Settled
2016 to Present	Client:	Casper, Meadows, Schwartz & Cook
	Case:	*Rovner v. Medtronic, Inc. et.al.* Contra Costa Superior Court, Case No. C16-01768
	Project:	Medical Device defect of NSC spinal lumboperitoneal (LP) Shunt/Valve for hydrocephalus shunting of excess cerebrospinal fluid (CSF); associated personal injury
	Status:	Settled
2016 to 2018	Client:	Rimon Law
	Case:	*Heather Ciechanowski v. Invacare Corporation, Folsom Care Center, Bluff Enterprises, Inc. and Calvin Callaway*, Sacramento County Superior Court Case No. 34-2016-00188724
	Project:	Alleged medical equipment product defect
	Status:	Settled
2016 to 2017	Client:	Rucka, O'Boyle, Lombardo & McKenna
	Case:	*Concepcion Hernandez v. Helen of Troy, Inc;*
	Project:	Medical equipment personal injury
	Status:	Settled

2016 to 2017	Client:	Quinn Emanuel Urquhart & Sullivan, LLP
	Case:	*TriReme Medical LLC v. AngioScore, Inc.*, Northern District of California; Case No. 14-cv-2946
	Project:	Patent litigation involving cardiovascular medical device
	Status:	Deposition, Dec.2016; Expert Reports, Nov.2016 & Dec.2016; Settled
2016 to Present	Client:	Baker Manock & Jensen, PC
	Case:	*California Fire-Roasted LLC v. General Mills Operations, LLC;* Sacramento County Superior Court Case No. 34-2014-00170784-CU-BC-GDS
	Project:	Patent licensing and royalty case for food-processing equipment
	Status:	Ongoing
2016 to 2017	Client:	DLA Piper, LLP
	Case:	*Inter Partes* Review of U.S. Patent No. 6,099,882; *Olam West Coast, Inc. v. California Fire-Roasted LLC*
	Project:	Patent IPR involving food-processing equipment
	Status:	IPR Declarations (2) Filed Oct.2016;
2016 to 2018	Client:	Plews Shadley Racher & Braun, LLP
	Case:	*Rick C. Sasso, M.D., and SEE LLC v. Warsaw Orthopedic, Inc., Medtronic Inc., Medtronic Sofamor Danek, Inc*, Indiana State Court, Case No. 43C01-1308-PL-44.
	Project:	Patent litigation involving coverage for spinal medical device
	Status:	Deposition Aug 2018; **Patent Trial Testimony Nov 2018**; Jury Verdict
2016 to Present	Client:	Christensen Fonder, P.A.
	Case:	*Willis Electric Co., Ltd v. Polygroup Limited (Macao Commercial Offshore), Polygroup Macau Limited (BVI), Polytree (H.K.) Co. Ltd.,* 15-cv-3443, 3:15-cv-00552, United States District Court for the District of Minnesota.
	Project:	Patent litigation involving modular mechanical and electrical connectors
	Status:	
2016 to Present	Client:	Locke Lord LLP
	Case	*Denneroll Holdings Pty Limited and Denneroll Industries International Pty Limited v. ChiroDesign Group, LLC and Marie L. Webster, Individually and D/B/A ChiroDesign Group;* Civil Action No. 4:15-cv-740; United States District Court for the Southern District of, Houston Division.
	Project:	Patent litigation involving chiropractic pillows
	Status:	Settled; Infringement Expert Report, May 2016; Validity Expert Report, June 2016

2016 to Present	Client:	Mass Montes LLP
	Case:	*Logan W. Hensley vs. Michael J. Skyhar, MD.; Cayenne Medical, Inc., and DOES 1 thru 40, inclusive;* Case no. 37-2015-00005140-CU-MM-NC, Superior Court for the State of California for the County of San Diego, North County Division.
	Project:	Personal injury involving failed medical device and medical practice
	Status:	Settled
2016 to Present	Client:	Hamrick & Evans, LLP
	Case:	*Laurence Johnson vs. Raytheon Company, Systems XT, Inc. Brownco Construction Company, Inc., Power Edge Solutions, Inc. (aka PES Controls), et.al.* United States District Court for the Central District of California; Case No. 2:15-cv-00132-MWF-E.
	Project:	Personal Injury; Product Performance & Product Liability
	Status:	Ongoing;
2015 to 2016	Client:	Nixon Peabody LLP
	Case:	*Johnstech International Corp v. JF Microtechnology SDN BHD* United States District Court for the Northern District of California; Case No. 3:14-cv-02864-JD
	Project:	Patent litigation involving semiconductor test technology
	Status:	Invalidity Expert Report, Non-Infringement Expert Report – Dec 2015; **Patent Trial Testimony – Sep 2016**. Jury Verdict.
2015	Client:	Susman Godfrey LLP
	Case:	*Bonutti Skeletal Innovations, LLC v. Globus Medical, Inc*
	Project:	Patent litigation involving spinal medical devices
	Status:	Ongoing
2015	Client:	Richardson, Patrick, Westbrook, & Brickman, LLC
	Case:	*Smart v. PACCAR*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled
2014 to 2018	Client:	Harris and Graves, P.A.
	Case:	*Dineen v. Sprint and Apple*
	Project:	Investigation of alleged cellular telephone defect and Lithium-Ion battery breach; Personal injury (victim sustained burns) due to ignition & combustion of cell phone; Non-Destructive & Destructive Inspections
	Status:	Settled Deposition Oct 2017; Expert Report, July 2015, July 2017;

2014 to 2019	Client:	Law Offices of David McQuade Leibowitz, P.C.
	Case:	*Ricardo Garza v. Daimler Truck of North America (DTNA), Freightliner LLC;* Texas Circuit Court, Bexar County, Texas
	Project:	Heavy Truck Crashworthiness
	Status:	Trial Testimony Sep 2019; Deposition Jul 2018; Expert Report Apr 2018; Jury Verdict;
2014	Client:	Kolisch Hartwell, P.C.
	Case:	*TMI Products, Inc. v. Rosen Entertainment Systems, L.P* United States District Court for the Central District of California; Case No. EDCV12-02263 RGK (SPx)
	Project:	Patent case involving consumer electronics & vehicle entertainment applications
	Status:	Settled; Deposition March 2014; Declaration & Report March 2014; Declaration & Rebuttal Report March 2014;
2014 to 2018	Client:	Corsiglia, McMahon, & Allard
	Case:	*Avalos v. Balt, Stanford Hospital & Clinics, et.al.*
	Project:	Personal Injury during Medical Procedure & Medical Device Product Liability; Failure analysis of micro-catheter for neurovascular treatment; embolization of a cerebral AVM during procedure at Stanford Hospital
	Status:	Settled
2014 to 2015	Client:	The Previant Law Firm, S.C.
	Case:	*Kaminski v. DongGuan, et.al.*
	Project:	Personal injury (eye damage) due to failure of consumer product (elastomeric strap tie-down); Failure analysis, material testing, and evaluation of elastomeric material components
	Status:	Settled; Expert Report, July 2014
2013 to 2015	Client:	Guajardo & Marks, LLP
	Case:	*Bertha A. Flores Individually and as Representative of the Estate of Jose Flores, et.al. v Daimler Trucks North America, LLC.* United States District Court for the Southern District of Texas, Corpus Christi Division, and is Civil Action No. 2:13-cv-87
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled, Mar 2015 Deposition, Feb 2015; Report, Oct 2014

2012 to 2014	Client:	Edwards Life Sciences; Kilpatrick, Townsend & Stockton, LLP
	Case:	*Medtronic v. Edwards* Case No. 11-CV-1650-JNE/JSM (D. Minn.)
	Project:	Medical device patent claims, infringement & invalidity
	Status:	Settled Invalidity Report Aug 2013; Non-Infringement Report Oct 2013; Deposition Oct 2013, Oct 2012
2013 to 2014	Client:	US Securities and Exchange Commission
	Case:	*Securities and Exchange Commission (SEC) v. Inteligentry, Ltd., Plasmerg, Inc., PTP Licensing, Ltd., and John P. Rohner in Civil No. 2:13-CV-00344-GMN-NJK*
	Project:	Securities associated with "Plasmic Transition Process Engine" technology; Technology assessment
	Status:	Resolved
2013 to 2015	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Walker v. PACCAR, Inc;* Alabama Circuit Court, Barbour County; 06-CV-2013-900032.00
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled
2013	Client:	Retained in a metal component manufacturing technology patent litigation case.
	Case:	*Confidential*
	Project:	Metal manufacturing process patent for smart-phone and consumer electronics applications
2013 to 2015	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Lacy v. Freightliner*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled Mar 2015
2013 to 2015	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Jones vs. Daimler Truck North America (DTNA)* Alabama Circuit Court
	Project:	Heavy Truck Rollover & Crashworthiness
	Status:	Settled Nov 2015; Deposition Jan 2014
2012	Client:	Smart-phone technology patent litigation case involving embedded electro-mechanical components
	Case:	*Confidential*
	Project:	Patent issues associated with specific user-feedback technologies
	Status:	

2010 to 2015	Client:	Warren & Associates, LLC
	Case:	*Jones vs. MSE Hauling*
	Project:	Heavy Truck Rollover
	Status:	Settled Nov 2015; Deposition Jan 2014
2009 to 2014	Client:	Schwarz & Mongeluzzi; Nelson, Levine, DeLuca & Horst
	Case:	*Carrera v. Navistar*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled 2014; Deposition Feb 2013
2010	Client:	Sico, White, Hoelscher & Braugh L.L.P.
	Case:	*Ramirez v. Sterling Truck*
	Project:	Heavy-Truck Rollover & Crashworthiness
	Status:	Settled; Expert Report; Deposition May 2010
2008 to 2010	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Thibadeaux vs. PACCAR*
	Project:	Heavy-Truck Rollover Accidents
	Status:	Settled; 2010.
2008 to 2010	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Price vs. Navistar*
	Project:	Heavy-Truck Rollover Accidents
	Status:	Settled; 2010.
2008 to 2009	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Martin vs. Kenworth*
	Project:	Heavy-Truck Rollover Accidents
	Status:	Settled; 2009.
2007	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Strode v. Freightliner, LLC;* Civil Action No. 02-132 Circuit Court of Greene County Alabama
	Project:	Heavy-Truck Rollover Accident
	Status:	Settled; 2007. Testified at trial.
2006	Client:	Gibson, Dunn, & Crutcher
	Case:	*Jang v. Boston Scientific Corp., et.al.* United States District Court, Central District of California; Eastern Division – Riverside; Case No: EDCV 05-00426 VAP (SGLx)
	Project:	Patent case for matters involving design features of Cardiovascular Stents.
	Status:	
2005	Client:	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.
	Case:	*Mongan vs. MACK Truck*
	Project:	Retained as fact witness in heavy truck rollover accident.
	Status:	Settled, 2005

2005	Client:	Lucas Wash Petway Tucker & Stephens, P.C.
	Case:	*Gable v. International Truck & Engine Corporation* United States District Court, Middle District of Pennsylvania; Civil Action No: 3:03-CV-01353
	Project:	Heavy-Truck Rollover Accident
	Status:	Closed; Deposition June 2005.
2004	Client:	Kenyon & Kenyon Intellectual Property Law Firm
	Case:	*Medtronic Vascular, Inc. vs. Boston Scientific Corp., et al.* C.A. No. 98-478-SLR (D-Del)
	Project:	Patent case involving Cardiovascular Stent design
	Status:	Closed; Expert Report filed; No Deposition.
1997	Client:	Grimaldi, Pearson,and Weyand, P.C.
	Case:	*Herbolsheimer v. Warner-Swasey* Case No. 9357487NP
	Project:	Product defect of CNC machine equipment
	Status:	Closed; Deposition.
1994	Client:	Jones, Jones, Close & Brown
	Case:	*Pioneer Chlor-Alkali Co., Inc. v. National Union Fire Insurance Co.*, United States District Court, District of Nevada, Case No. CV-S-93-276-HDM (RLH)
	Project:	Accident investigation, insurance claim.
	Status:	Closed; Deposition.
1994	Client:	Clapp, Moroney, Bellagamba, Davis and Vucinich
	Case:	*Thomas Fujisaka and Sandra Fujisaka v. Livermore Valley Unified School District*, Superior Court of the State of California In and For the County of Alameda, Case No. 700921-1
	Project:	Accident Investigation, Personal Injury
	Status:	Closed; Deposition.
1994	Client:	GEA In-House Counsel
	Case	*GEA Power Cooling Systems, Inc. v. Hyspan Precision Products*, Superior Court of the State of California for the County of San Diego, Case No. 669769
	Project:	Product Liability; Failure analysis root cause.
	Status:	Closed; Deposition.
1993	Case	*Bobbye J. Phaneuf v. Edith D. Roman*, Superior Court of the State of California County of Alameda, Case No. H - 154330-4
	Project:	Product Design.
	Status:	Closed; Deposition, Trial.

1993	Case:	*Patricia C. Barbera v. H. B. Instrument Company*, Superior Court of the State of California In and For the County of Marin, Case No. 138929
	Project:	Product Design.
	Status:	Closed; Deposition, Trial.
1990	Client:	Chevron In-House Counsel
	Case:	*Secretary of Labor v. Chevron U.S.A, et al.*, Occupational Safety and Health Review Commission, Region 9, OSHRC Docket No. 89-3125
	Project:	Accident investigation; Failure analysis root cause.
	Status:	Closed; Deposition.

Trials & IPRs:

2018	Case:	*Ricardo Garza v. Daimler Truck of North America (DTNA), Freightliner LLC;* Texas Circuit Court, Bexar County, Texas
	Status:	Testified in Trial, Sep 2019
2018	Case:	*Lite-On Technology Corp v Darfon Electronics Corp,* Case No. 3:18-cv-02776, United States District Court, Northern District of California.
	Status:	IPR Declaration Dec 2018;
2018	Case:	*Rick C. Sasso, M.D., and See LLC v. Warsaw Orthopedic, Inc., Medtronic Inc., Medtronic Sofamor Danek, Inc*, Indiana State Court, Case No. 43C01-1308-PL-44.
	Status:	Testified in Patent Trial, Nov 2018
2018	Case:	*SCA Hygiene Products AB et.al., SCA Tissue North America, LLC v. Tarzana Enterprises, LLC;* United States District Court, Western District of Wisconsin, No. 3:16-cv-00728
	Status:	IPR Response Declarations, July 2018 (2), May 2018;
2018	Case:	Davidson, Davidson & Kappel LLC; ArcelorMittal Project
	Status:	IPR Declaration, Mar 2018;
2017	Case:	*Trans Technologies Company v. Hendrickson USA LLC, et.al.*, United States District Court for the Northern District of Georgia, Atlanta Division, Civil Action No. 1:16-cv-01778-AT
	Status:	IPR Declaration Aug 2017; IPR Response Declaration Feb 2018;
2017	Case:	*Lenovo (United States) Inc. v. Blackbird Tech d/b/a Blackbird Technologies*, Review of U.S. Patent No. 7,129,931;
	Status:	IPR Declaration May 2017;

2016	Case:	*Olam West Coast, Inc. v. California Fire-Roasted LLC; Inter Partes* Review of U.S. Patent No. 6,099,882
	Status:	IPR Declarations (2), Oct 2016;
2016	Case:	*Johnstech International Corp. v. JF Microtechnology SDN BHD;* Action 14-cv-02864-JD, US Federal Court, District of Northern California
	Status:	Testified in Patent Trial, Sep 2016
2007	Case:	*Strode v. Freightliner, LLC;* Civil Action No. 02-132 Circuit Court of Greene County Alabama
	Status	Testified in Product Liability/Personal Injury case;
1995	Case:	*Bobbye J. Phaneuf v. Edith D. Roman*; Superior Court of the State of California County of Alameda, Case No. H-154330-4
	Status:	Testified in Product Liability/Personal Injury case;
1994	Case:	*Patricia C. Barbera v. H. B. Instrument Company*; Superior Court of the State of California In and For the County of Marin, Case No. 138929
	Status:	Testified in Product Liability case;

Exhibit B

Exhibit B

Materials Considered

- "303 Stainless Steel." Penn Stainless, 5 Dec. 2018, www.pennstainless.com/resources/product-information/stainless-grades/300-series/303-stainless-steel/.
- "Access and instruments product catalog" Medtronic, 2020, available at: https://www.medtronic.com/content/dam/covidien/library/us/en/product/hand-instruments-and-ligation/access-instrumentation-products-catalog.pdf.
- "Engineering Failure Analysis, Fatigue & Mechanical Tests: DNV Labs." *DNV*, www.dnv.com/oilgas/laboratories-test-sites/engineering-failure-analysis-fatigue-tests-and-mechanical-tests-dnvgl-labs-hovik.html.,
- Anderson, Patrick L., et al. "Robot-like Dexterity without Computers and Motors: a Review of Hand-Held Laparoscopic Instruments with Wrist-like Tip Articulation." Expert Review of Medical Devices, vol. 13, no. 7, 2016, pp. 661–672., doi:10.1586/17434440.2016.1146585., at page
- "Expanding the Reach of Surgery," Medrobotics "Flex" brochure, available at: https://www.easmed.com/main/wp-content/uploads/BROCHURE-Medrobotics-Transanaleasmed.pdf
- "Failure Analysis Testing: Engineering Failure Analysis |." *Stress Engineering Services, Inc*, 14 Feb. 2020, www.stress.com/capabilities/materials-engineering/failure-analysis/
- "Flex Robotic System Technology: How it Works," available at: https://medrobotics.com/gateway/technology/
- "Flexible 'open architecture' instrumentation," available at: https://medrobotics.com/gateway/instruments/
- "Tungsten." *Elmet Technologies*, www.elmettechnologies.com/tungsten/.
- Center for Devices and Radiological Health. "A History of Medical Device Regulation and Oversight in the US." *U.S. Food and Drug Administration*, FDA, www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states.
- Center for Devices and Radiological Health. "Current Good Manufacturing Practice Final Rule; Quality System." *U.S. Food and Drug Administration*, FDA, www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices/medical-devices-current-good-manufacturing-practice-cgmp-final-rule-quality-system-regulation.
- Deciding When to Submit a 510(k) for a Change to an Existing Device; Guidance for Industry and Food and Drug Administration Staff, issued on October 25, 2017
- Koukourikis P, Rha KH. Robotic surgical systems in urology: What is currently available? Investigative and Clinical Urology. 2021

- Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, https://www.fda.gov/media/116573/download
- DS2505 Dallas Semiconductor data sheet, available at: https://datasheets.maximintegrated.com/en/ds/DS2505.pdf
- Remanufacturing of Medical Devices: Draft Guidance for Industry and Food and Drug Administrative Staff, issued on June 18, 2021
- Richard G. Budynas and J. Keith Nisbett, Shigley's Mechanical Engineering Design, Ninth Edition, McGraw-Hill, New York, 2008
- Ruurda, Jelle P., et al. "Analysis of Procedure Time in Robot-Assisted Surgery: Comparative Study in Laparoscopic Cholecystectomy." *Computer Aided Surgery*, vol. 8, no. 1, 2003, pp. 24–29., doi:10.3109/10929080309146099.
- Safe Medical Devices Act of 1990
- Scheer, Adena, et al. "Laparoscopic Colon Surgery: Does Operative Time Matter?" Diseases of the Colon & Rectum, vol. 52, no. 10, 2009, pp. 1746–1752., doi:10.1007/dcr.0b013e3181b55616.
- Senhance Surgical System EMEA Product Catalog, January 2020 Senhance.com/indications
- Shigley's Wire Rope Chapter
- Shushan A, Mohamed H, Magos AL. How long does laparoscopic surgery really take? Lessons learned from 1000 operative laparoscopies. Hum Reprod. 1999 Jan;14(1):39-43. doi: 10.1093/humrep/14.1.39. PMID: 10374091.
- Steel, Alro. "303 Stainless Steel." *303 Stainless Steel | Chromium-Nickel Stainless Steel | Alro Steel*, www.alro.com/divsteel/metals_gridpt.aspx?gp=0117
- U.S. Navy Wire-Rope Handbook, Vol. 1
- Urology-robot-compare-icu-62-14
- Medical Device Amendments of 1976
- Medical Device Reporting for Manufacturers – Guidance for Industry and Food and Drug Administration Staff
- Medtronic-access-instrumentation-products-catalog
- Premarket Notification 510(k)
- Rebotix Complaint (ECF No. 1)
- Rebotix's Supplemental Responses and Objections to Intuitive's First Set of Interrogatories
- FDA website provides a description of MAUDE: (https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacturer-and-user-facility-device-experience-database-maude
- Fiegel Conversation
- Intuitive Manufacturing Process Instructions (MPI) Cable Tensioning, 838012
- Intuitive's Answer, Affirmative Defenses and Counterclaims (ECF No. 49)
- June 15th, 2021, Deposition of Bob Overmars (with accompanying exhibits)

- June 22nd, 2021, Deposition of Chris Gibson (with accompanying exhibits)
- June 2nd, 2021, Deposition of Glenn Papit (with accompanying exhibits)
- June 4th, 2021, Deposition of Mark Johnson (with accompanying exhibits)
- June 7th, 2021, Deposition of Anthony McGrogan (with accompanying exhibits)
- May 14th, 2021, Deposition of Glenn Vavoso (with accompanying exhibits)
- May 24th, 2021, Deposition of Edward W. Harrich (with accompanying exhibits)
- May 26th, 2021, Deposition of Katie Scoville (with accompanying exhibits)
- May 27th, 2021, Deposition of Bob DeSantis (with accompanying exhibits)
- May 27th, 2021, Deposition of Stacey Donovan (with accompanying exhibits)
- May 7th, 2021, Deposition of Myriam Curet (with accompanying exhibits)
- June 6th, 2021, Deposition of Chris Gibson (with accompanying exhibits)
- June 14th, 2021, Deposition of Joe Morris (with accompanying exhibits)
- June 4th, 2021, Deposition of Stan Hamilton (with accompanying exhibits)
- 1906 Pure Food and Drugs Act
- 2018 FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices
- 21 CFR § 803
- 21 CFR § 807.3
- 21 CFR § 807.81
- 21 CFR § 820
- 21 CFR § 820.198
- 21 CFR § 830
- BB000011
- BB000070
- BB000072
- BB000082
- BB000161
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- Intuitive-00695006
- REBOTIX000664
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- REBOTIX004895
- REBOTIX045741
- REBOTIX048397
- REBOTIX060630
- REBOTIX068469
- REBOTIX068497
- REBOTIX068498
- REBOTIX074001
- REBOTIX074063
- REBOTIX075420
- REBOTIX075431-075433
- REBOTIX077469
- REBOTIX078437
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- REBOTIX089521
- REBOTIX089889
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- REBOTIX090153
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- REBOTIX090161-090162
- REBOTIX090164
- REBOTIX090166
- REBOTIX092208
- REBOTIX100861
- REBOTIX100995
- REBOTIX111490
- REBOTIX119271
- REBOTIX119844
- REBOTIX121303
- REBOTIX122260
- REBOTIX123411
- REBOTIX123447
- REBOTIX123448
- REBOTIX123792
- REBOTIX123794
- REBOTIX124268-REBOTIX124431
- REBOTIX124268-REBOTIX124705
- REBOTIX124432-REBOTIX124479
- REBOTIX124467-REBOTIX124705
- REBOTIX124718-REBOTIX124756
- REBOTIX124718-REBOTIX124756
- REBOTIX125438-REBOTIX125759
- REBOTIX126040-REBOTIX126237
- REBOTIX126238-REBOTIX126239
- REBOTIX126238-REBOTIX126390
- REBOTIX126240-REBOTIX126293

- REBOTIX126294-REBOTIX126335
- REBOTIX126336-REBOTIX126390
- REBOTIX126788-REBOTIX127430
- REBOTIX128851
- REBOTIX129043
- REBOTIX132017-REBOTIX132562
- REBOTIX132019
- REBOTIX132477
- REBOTIX132559
- REBOTIX132562
- REBOTIX133038
- REBOTIX133235-REBOTIX133311
- REBOTIX133337- REBOTIX133353
- REBOTIX133344
- REBOTIX133344
- REBOTIX133373
- REBOTIX134639
- REBOTIX134642
- REBOTIX134655-134656
- REBOTIX134750-REBOTIX134754
- REBOTIX139107
- REBOTIX146770
- REBOTIX146770-REBOTIX146781
- REBOTIX146771
- REBOTIX146884-REBOTIX146946
- REBOTIX146926
- REBOTIX146940
- REBOTIX146956
- REBOTIX146958
- REBOTIX151910-REBOTIX151917
- REBOTIX151919-REBOTIX151920
- REBOTIX151919-REBOTIX151922
- REBOTIX151921-REBOTIX151922
- REBOTIX151966-REBOTIX152018
- REBOTIX152284
- REBOTIX153047
- REBOTIX153993-REBOTIX154019
- REBOTIX154322
- REBOTIX155261-REBOTIX155521
- REBOTIX155868

- REBOTIX156431-REBOTIX156446
- REBOTIX156431-REBOTIX156495
- REBOTIX157893
- REBOTIX160706
- REBOTIX162185
- REBOTIX162228
- REBOTIX162404
- REBOTIX162404-REBOTIX162424
- REBOTIX162405
- REBOTIX162422
- REBOTIX162439
- REBOTIX162441
- REBOTIX162442-162443
- REBOTIX162444
- REBOTIX162889
- REBOTIX165979-REBOTIX165998
- REBOTIX166019
- REBOTIX170053
- REBOTIX170058
- REBOTIX17006
- REBOTIX170067
- REBOTIX170075-170076
- REBOTIX170077-170078
- REBOTIX170136
- REBOTIX170283-170284
- REBOTIX170283-REBOTIX170284
- REBOTIX174749-REBOTIX174756
- REBOTIX175327
- REBOTIX175327
- Expert Report of Dr. Joshua Sharlin Report
- Expert Report of Dr. Robert Howe Report
- Rebotix's Responses and Objections to Intuitive's Second Set of Interrogatories
- Rebotix's Supplemental Responses and Objections to Intuitive's First Set of Interrogatories
- US Patent No. 5,797,900
- US Patent No. 6,991,627